EXHIBIT 27

From: Hudson, Brian [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=BHUDSON]
Date: 12/10/2003 12:20:18 AM
To: DeCant, Len [Len.DeCant@crbard.com], Casanova, Mike [Mike.Casanova@crbard.com], Carr, Robert [Robert.Carr@crbard.com], Tessmer, Alex [Alex.Tessmer@crbard.com]
CC: Uelmen, Doug [Doug.Uelmen@crbard.com], Hudnall, Janet [Janet.Hudnall@crbard.com]
Subject: Special Design Review for Recovery - Meeting Minutes
Attachments: MeetingMinutes.DOC

All,

Attached are the meeting minutes for the Special Design Review for Recovery (Project #'s 7081 and 8008). Please review and provide feedback if necessary.

Thanks,

Brian

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MEMORANDUM

TO: Len DeCant, Mike Casanova, Rob Carr, and Alex Tessmer

CC: Doug Uelmen, Janet Hudnall, Project #7081 - Fact Book, and Project #8008 – Fact Book

FROM: BRIAN HUDSON

DATE: DECEMBER 9TH, 2003

SUBJECT: Special Design Review for Recovery (Project #'s 7081 and 8008) - Meeting Minutes

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A special design review meeting was held on Friday December 5th, 2003 to discuss the Recovery® Filter and Cone projects (Filter - #7081 and Cone - #8008). The purpose of this special review was to gain further understanding related to the design elements of these products in anticipation of the up and coming Full Market Release (FMR) in January of 2004.

NOTE: It is important to point out that this review did not cover the topics of Design Review IV. A separate review will be held, prior to launch, that will cover these topics.

The elements that were reviewed during the meeting are outlined in an earlier memorandum entitled, "Special Design Review for Recovery (Project #'s 7081 and 8008) – Objectives", dated December 4th, 2003. As defined in the previous memorandum, the level of review was based upon the degree of risk obtained from the Design Failure Modes and Effect Analysis (DFMEA) for the Recovery Filter (DFMEA070010) and Recovery Cone (DFMEA070011). All elements identified in the previous memorandum were discussed during the review meeting.

The following action items resulted from this meeting:

1. Related to the issue of ***deployment force***, the review team would like to see some objective evidence of what the actual deployment force is with the current product. The team would also like to see an acceptance criterion established and added to the Product Performance Specification (PPS) for the Recovery Filter.

2. Related to the issue of ***partial deployment***, the review team fells that the current severity ranking of "3" for this potential failure mode is not accurate. The review team requests that Part 1/Section 3.2 of DFMEA070010 be update with a severity ranking of "4".

3. Related to the issue of ***Migration***, the review team would like to see objective evidence of the following elements:

    a. Documentation that explains the establishment of the 50 mmHg acceptance criteria for migration resistance.

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b. A migration resistance study that analyzes the performance of the Recovery Filter in conjunction with tilting and quantity of legs/hooks.

c. A migration resistance study that compares the Recovery Filter to competitive products (e.g., Greenfield).

d. A radial force study that compares the Recovery Filter to competitive products (e.g., Greenfield).

e. A migration resistance study on Recovery Filter product that was manufactured at Bard Glens Falls Operations (GFO) as opposed to Nitinol Medical Technologies (NMT), Inc.

f. A migration resistance study that analyzes the performance of the Recovery Filter in conjunction with oval and/or D-shaped IVC tracks (and transitions between these configurations).

4. Related to the issue of ***patency***, the review team would like to see objective evidence of the flow characteristics of the Recovery Filter in its intended environment.

5. Related to the issue of ***hook dimensions***, the review team would like to see objective evidence in regards to the design input history of the hook dimensions.

These action items will be subsequently reviewed at the next design review meeting for the Recovery Filter project. None of the action items were related to the Recovery Cone and thus this requirement does not extend to that project.

Brian Hudson_____
Sr. Quality Assurance Engineer - Endovascular

1625 West 3rd Street • P. O. Box 1740 • Tempe, AZ 85280-1740
Tel: 1-800-321-4254 • 1-480-894-9515 • Fax: 1-480-966-7062 • www.bardpv.com

EXHIBIT 28

From: Rauch, David [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=DRAUCH]
Date: 2/27/2004 5:21:55 PM
To: Hudnall, Janet [Janet.Hudnall@crbard.com]
Subject: RE: Case for Caval Centering
Attachments: Rauch, David.vcf

Janet,
Thank-you for your valuable feedback. You are right; now that we have more experience with Recovery the positioning of tilt-resistance should probably be down played.
I will work on implementing your suggestions as well as those of the trainers and let you see the revised copy when it is done.

Dave Rauch
Bard Peripheral Vascular

-----Original Message-----
From: Hudnall, Janet
Sent: Thursday, February 26, 2004 2:01 PM
To: Rauch, David
Subject: Case for Caval Centering

Dave,

I wanted to comment on the training piece that you created. First of all, I'd like to applaud you for having pulled together a lot of good information.

Having said that, however, I must strongly caution against emphasizing Recovery's ability to center in the cava to the point where it is the focus of the product's positioning. We knew very little about the long-term clinical performance of this device when we launched it. After a year of commercialization, there are still many questions that need to be answered. One thing that we do know, however, is that Recovery does not always stay centered in the cava. In fact, physicians will often find that it is tilted quite a bit when they go to retrieve it even though it seemed perfectly centered upon deployment. So it seems to me that selling the device solely on this feature could set the sales rep up for some uncomfortable situations in the long run.

My opinion is that your document would be, in general, okay if it were positioned differently so that centering is not the focal point of its features and benefits. Also, I think that for a piece like this, it is critical to carefully reference the entire body of the text so that the reader can differentiate between what is documented in the literature and what is anecdotal/opinion.

Regards,
Janet

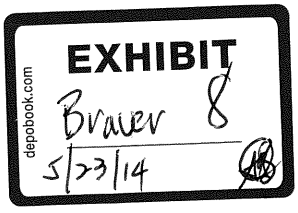


EXHIBIT 30

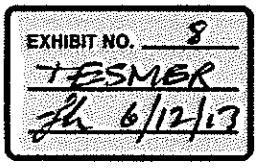
From: Tessmer, Alex [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=ATESSMER]
Date: 2/25/2004 12:26:33 AM
To: Carr, Robert [Robert.Carr@crbard.com], Hudson, Brian [Brian.Hudson@crbard.com]
Subject: Filter Migration Test Results
Attachments: Migration15mm.xls, Migration21mm.xls, Migration25mm.xls, Migration28mm.xls

Rob and Brian,

I have attached the most current results.

Alex

Alex Tessmer
Bard Peripheral Vascular
Research & Development
Engineer II
1415 West 3rd Street, Suite 109
Tempe, AZ 85281
Direct: 480-303-2704
FAX: 480-449-2597
Email: <mailto:alex.tessmer@crbard.com> alex.tessmer@crbard.com



Sample ID #	Lot No.	Run No.	Pressure at Filter Migration (psi)	Pressure at Filter Migration (mmHg)	Testing Temp (°C)	Tube Diameter (mm)
RF1	07KN2852	1	0.85	44.0	37 ± 2	28
		2	0.90	46.5	37 ± 2	28
		3	1.07	55.3	37 ± 2	28
RF2	07KN2852	1	0.62	32.1	37 ± 2	28
		2				
		3				
RF3	07KN2852	1	0.14	7.2	37 ± 2	28
		2	0.89	46.0	37 ± 2	28
		3	0.89	46.0	37 ± 2	28
RF4	07KN2852	1	0.70	36.2	37 ± 2	28
		2	0.63	32.6	37 ± 2	28
		3	0.70	36.2	37 ± 2	28
RF5	07KN2852	1	0.87	45.0	37 ± 2	28
		2	0.56	29.0	37 ± 2	28
		3	1.13	58.4	37 ± 2	28
RF6	07KN2852	1	0.92	47.6	37 ± 2	28
		2	1.02	52.7	37 ± 2	28
		3	1.36	70.3	37 ± 2	28
RF7	07KN2852	1	0.84	43.4	37 ± 2	28
		2	0.97	50.2	37 ± 2	28
		3	0.96	49.6	37 ± 2	28
RF8	07KN2852	1	0.80	41.4	37 ± 2	28
		2	0.88	45.5	37 ± 2	28
		3	1.28	66.2	37 ± 2	28
RF9	07KN2852	1	0.95	49.1	37 ± 2	28
		2	0.90	46.5	37 ± 2	28
		3	0.71	36.7	37 ± 2	28
RF10	07KN2852	1	1.12	57.9	37 ± 2	28
		2	0.90	46.5	37 ± 2	28
		3	0.89	46.0	37 ± 2	28
RF11	07KN2852	1	1.00	51.7	40 ± 3	28
		2	1.36	70.3	40 ± 3	28
		3	1.29	66.7	40 ± 3	28
RF12	07KN2852	1	0.54	27.9	40 ± 3	28
		2	1.01	52.2	40 ± 3	28
		3	1.21	62.6	40 ± 3	28
RF13	07KN2852	1	1.26	65.2	40 ± 3	28
		2	1.15	59.5	40 ± 3	28
		3	1.24	64.1	40 ± 3	28
RF14	07KN2852	1	1.37	70.8	40 ± 3	28
		2	0.80	41.4	40 ± 3	28
		3	0.91	47.1	40 ± 3	28
RF15	07KN2852	1	1.05	54.3	40 ± 3	28
		2	0.67	34.6	40 ± 3	28
		3	0.82	42.4	40 ± 3	28
RF16	07KN2852	1	1.01	52.2	40 ± 3	28
		2	0.85	44.0	40 ± 3	28
		3	1.07	55.3	40 ± 3	28
RF17	07KN2852	1	0.67	34.6	40 ± 3	28
		2	1.19	61.5	40 ± 3	28
		3	0.92	47.6	40 ± 3	28
RF18	07KN2852	1	0.62	32.1	40 ± 3	28
		2	1.08	55.9	40 ± 3	28
		3	0.84	43.4	40 ± 3	28
RF19	07KN2852	1	0.83	42.9	40 ± 3	28
		2	0.69	35.7	40 ± 3	28
		3	1.31	67.7	40 ± 3	28
RF20	07KN2852	1	1.21	62.6	40 ± 3	28
		2	1.00	51.7	40 ± 3	28
		3	0.91	47.1	40 ± 3	28

Data Summary		
Average	45.2	mmHg
Std Dev	12.07	
Min	7.2	
Max	70.3	
Average	51.5	mmHg
Std Dev	12.05	
Min	27.9	
Max	70.8	

Sample ID #	Lot No.	Run No.	Pressure at Filter Migration (psi)	Pressure at Filter Migration (mmHg)	Testing Temp (°C)	Tube Diameter (mm)
SF1	07JN2673	1	1.37	70.8	37 ± 2	28
		2	2.01	103.9	37 ± 2	28
		3	1.21	62.6	37 ± 2	28
SF2	07JN2673	1	1.08	55.9	37 ± 2	28
		2	1.67	86.4	37 ± 2	28
		3	1.04	53.8	37 ± 2	28
SF3	07JN2673	1	0.65	33.6	37 ± 2	28
		2	1.69	87.4	37 ± 2	28
		3	2.20	113.8	37 ± 2	28
SF4	07JN2673	1	1.64	84.8	37 ± 2	28
		2	1.38	71.4	37 ± 2	28
		3	1.43	74.0	37 ± 2	28
SF5	07JN2673	1	1.27	65.7	37 ± 2	28
		2	0.96	49.6	37 ± 2	28
		3	1.75	90.5	37 ± 2	28
SF6	07JN2673	1	1.04	53.8	37 ± 2	28
		2	1.63	84.3	37 ± 2	28
		3	3.47	179.5	37 ± 2	28
SF7	07JN2673	1	1.50	77.6	37 ± 2	28
		2	1.93	99.8	37 ± 2	28
		3	1.10	56.9	37 ± 2	28
SF8	07JN2673	1	1.59	82.2	37 ± 2	28
		2	1.59	82.2	37 ± 2	28
		3	1.48	76.5	37 ± 2	28
SF9	07JN2673	1	0.62	32.1	37 ± 2	28
		2	1.14	59.0	37 ± 2	28
		3	2.03	105.0	37 ± 2	28
SF10	07JN2673	1	1.80	93.1	37 ± 2	28
		2	1.14	59.0	37 ± 2	28
		3	0.83	42.9	37 ± 2	28

Data Summary		
Average	76.3	mmHg
Std. Dev	28.45	
Min	32.1	
Max	179.5	

SF1	07JN2673	1	1.00	51.7	40 ± 3	28
		2	2.47	127.7	40 ± 3	28
		3	0.98	50.7	40 ± 3	28
SF2	07JN2673	1	1.58	81.7	40 ± 3	28
		2	1.45	75.0	40 ± 3	28
		3	1.35	69.8	40 ± 3	28
SF3	07JN2673	1	2.05	106.0	40 ± 3	28
		2	2.39	123.6	40 ± 3	28
		3	1.84	95.2	40 ± 3	28
SF4	07JN2673	1	1.60	82.7	40 ± 3	28
		2	2.13	110.2	40 ± 3	28
		3	1.72	88.9	40 ± 3	28
SF5	07JN2673	1	1.98	102.4	40 ± 3	28
		2	1.69	87.4	40 ± 3	28

Average	89.1	mmHg
Std. Dev	22.86	

		3	2.39	123.6	40 ± 3	28	Min	48.1	
SF6	07JN2673	1	0.93	48.1	40 ± 3	28	Max	140.1	
		2	1.70	87.9	40 ± 3	28			
		3	1.85	95.7	40 ± 3	28			
SF7	07JN2673	1	1.47	76.0	40 ± 3	28			
		2	1.65	85.3	40 ± 3	28			
		3	1.13	58.4	40 ± 3	28			
SF8	07JN2673	1	1.50	77.6	40 ± 3	28			
		2	2.71	140.1	40 ± 3	28			
		3	1.69	87.4	40 ± 3	28			
SF9	07JN2673	1	2.17	112.2	40 ± 3	28			
		2	1.64	84.8	40 ± 3	28			
		3	1.72	88.9	40 ± 3	28			
SF10	07JN2673	1	1.36	70.3	40 ± 3	28			
		2	2.01	103.9	40 ± 3	28			
		3	1.56	80.7	40 ± 3	28			

Sample ID #	Lot No.	Run No.	Pressure at Filter Migration (psi)	Pressure at Filter Migration (mmHg)	Testing Temp (°C)	Tube Diameter (mm)
VT1	F0507080	1	1.60	82.7	37 ± 2	28
		2	1.69	87.4	37 ± 2	28
		3	1.61	83.3	37 ± 2	28
VT1	F0507080	1	1.30	67.2	40 ± 3	28
		2	2.60	134.5	40 ± 3	28
		3	2.06	106.5	40 ± 3	28
VT2	F0507080	1	1.28	66.2	40 ± 3	28
		2	1.47	76.0	40 ± 3	28
		3	0.97	50.2	40 ± 3	28
VT3	F0507080	1	0.87	45.0	40 ± 3	28
		2	1.14	59.0	40 ± 3	28
		3	1.61	83.3	40 ± 3	28

Data Summary		
Average	84.5	mmHg
Std. Dev	2.55	
Min	82.7	
Max	87.4	
Average	76.4	mmHg
Std. Dev	28.49	
Min	45.0	
Max	134.5	

Sample ID #	Lot No.	Run No.	Pressure at Filter Migration (psi)	Pressure at Filter Migration (mmHg)	Testing Temp (°C)	Tube Diameter (mm)
GS1	6115450	1	1.65	85.3	40 ± 3	28
		2	2.18	112.7	40 ± 3	28
		3	2.15	111.2	40 ± 3	28
GS2	6115450	1	1.15	59.5	40 ± 3	28
		2	1.57	81.2	40 ± 3	28
		3	2.12	109.6	40 ± 3	28
GS3	6115450	1	1.82	94.1	40 ± 3	28
		2	1.83	94.6	40 ± 3	28
		3	1.17	60.5	40 ± 3	28

Data Summary		
Average	89.9	mmHg
Std. Dev	20.28	
Min	59.5	
Max	112.7	

Sample ID#	Lot No.	Run No.	Pressure at Filter Migration (psi)	Pressure at Filter Migration (mmHg)	Testing Temp (°C)	Tube Diameter (mm)
GT1	6113410	1	2.25	116.4	37 ± 2	28
		2	1.80	93.1	37 ± 2	28
		3	2.33	120.5	37 ± 2	28
GT1	6113410	1	2.06	106.5	40 ± 3	28
		2	1.07	55.3	40 ± 3	28
		3	1.70	87.9	40 ± 3	28
GT2	6113410	1	1.05	54.3	40 ± 3	28
		2	1.76	91.0	40 ± 3	28
		3	2.71	140.1	40 ± 3	28
GT3	6113410	1	1.24	64.1	40 ± 3	28
		2	2.07	107.0	40 ± 3	28
		3	1.94	100.3	40 ± 3	28

Data Summary		
Average	110.0	mmHg
Std. Dev	14.78	
Min	93.1	
Max	120.5	
Average	89.6	mmHg
Std. Dev	28.14	
Min	54.3	
Max	140.1	

Sample ID #	Lot No.	Run No.	Pressure at Filter Migration (psi)	Pressure at Filter Migration (mmHg)	Testing Temp (°C)	Tube Diameter (mm)
TP1	1309079	1	0.90	46.5	37 ± 2	28
		2	1.05	54.3	37 ± 2	28
		3	1.03	53.3	37 ± 2	28
TP1	1309079	1	0.61	31.5	40 ± 3	28
		2	0.36	18.6	40 ± 3	28
		3	0.87	45.0	40 ± 3	28
TP2	1309079	1	0.50	25.9	40 ± 3	28
		2	1.16	60.0	40 ± 3	28
		3	0.98	50.7	40 ± 3	28
TP3	1309079	1	1.06	54.8	40 ± 3	28
		2	0.79	40.9	40 ± 3	28
		3	1.10	56.9	40 ± 3	28

Data Summary		
Average	51.4	mmHg
Std. Dev	4.21	
Min	46.5	
Max	54.3	
Average	42.7	mmHg
Std. Dev	14.61	
Min	18.6	
Max	60.0	

Sample ID#	Lot No.	Run No.	Pressure at Filter Migration (mmHg)	Testing Temp (°C)	Tube Diameter (mm)
T1	R1103502	1	124.6	40 ± 3	28
		2	106.8	40 ± 3	28
		3	106.4	40 ± 3	28
T2	R1103502	1	95.6	40 ± 3	28
		2	118.2	40 ± 3	28
		3	113.3	40 ± 3	28
T3	R1103502	1	140.1	40 ± 3	28
		2	155.0	40 ± 3	28
		3	146.5	40 ± 3	28

Data Summary		
Average	122.9	mmHg
Std. Dev	20.24	
Min	95.6	
Max	155.0	

Sample ID#	Lot No.	Run No.	Pressure at Filter Migration (mmHg)	Testing Temp (°C)	Tube Diameter (mm)
O1	R0603592	1	155.0	40 ± 3	28
		2	114.0	40 ± 3	28
		3	155.0	40 ± 3	28
O2	R0603592	1	155.0	40 ± 3	28
		2	155.0	40 ± 3	28
		3	111.3	40 ± 3	28
O3	R0603592	1	127.8	40 ± 3	28
		2	128.0	40 ± 3	28
		3	128.6	40 ± 3	28

Data Summary		
Average	136.6	mmHg
Std. Dev	18.44	
Min	111.3	
Max	155.0	

EXHIBIT 31

BARD
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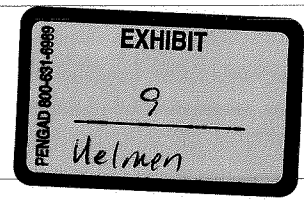
Engineering Test Report Number

ETR-04-03-02
REV 0

Characterization of Recovery Filter Migration Resistance in Comparison to Competitive Product
Phase 1



1.0 OBJECTIVE / PURPOSE OF TEST

The objective of this study was to compare the Recovery Filter (RF) to competitive products in relationship to migration resistance.

2.0 INTRODUCTION / BACKGROUND INFORMATION

The design of the Recovery Filter was originally challenged for migration resistance capabilities by Nitinol Medical Technologies (NMT), the original design facility. The results of NMT's testing indicated that both the Simon Nitinol Filter and RF products were able to resist migration at the minimum pressure of 50 mmHg (predefined acceptance criteria) in 15 and 28mm diameter mock vessels (ref. 3.3 and 3.4).

Recent field activities indicate that migration failures have been reported for the RF product. Therefore, further testing of this specific characteristic is warranted.

In conjunction with the field activities, a special Design Review was held on December 5th of 2003 to gain a further understanding of the design elements of this product. In preparation for the special Design Review, the DFMEA for Recovery Filter was analyzed for critical elements to be discussed during the review (ref. 3.1). Migration resistance was one of the critical elements identified for review. The outcome from this special Design Review was a list of action items, many of which were related to migration resistance (ref. 3.2).

One of the action items was to characterize the Recovery Filter migration resistance in comparison with competitive product (ref. 3.5).

3.0 REFERENCE DOCUMENTS

3.1 Memorandum entitled "Design Review Objectives for Recovery FMR launch (Project #'s 7081 and 8008)", dated December 4th, 2003.
3.2 Memorandum entitled "Special Design Review for Recovery (Project #'s 7081 and 8008) Meeting Minutes", dated December 9th, 2003.
3.3 RF Migration Study, Design Verification (RD-RPT-100)
3.4 IVC Filter Migration Study (RD-SOP-035.02)

4.0 TEST PROCEDURE

Test protocol TPR-04-02-02 was followed with the deviations as noted in section 6.0. The phase 1 portion of testing is summarized in this report. The phase 1 testing included testing migration resistance of the following products: Bard Recovery Filter, Bard Simon Nitinol Filter, Boston Scientific Greenfield Stainless Steel, Boston Scientific Greenfield Titanium, B-Braun Vena Tech, Cook Gűnther Tulip, Cordis TrapEase, and Cordis OptEase. The filters were tested in the following simulated IVC diameters: 15mm, 18mm, 21mm, 25mm, 28mm, 30mm, and 32mm.

5.0 TEST MATERIALS

5.1 Number of Samples:

A minimum of 38 samples were evaluated as part of this study.

5.2 Sample Size/Sample Grouping Rationale:

The following samples sizes and groups were identified as test samples:

Qty.	Manufacturer	Description
10	C.R. Bard	Recovery Filter
10	C.R. Bard	Simon Nitinol Filter
3	Boston Scientific	Greenfield (Titanium)
3	Boston Scientific	Greenfield (Stainless Steel)
3	B-Braun	Vena Tech LP
3	Cook	Gűnther Tulip
3	Cordis	OptEase
3	Cordis	TrapEase
10	NMT	Recovery Filter (Tested only in 28mm tubing)

It became necessary to replace filters when struts and major deformation occurred. New samples were given IDs in subsequent order. In some cases, the sample size increased.

5.3 Sample Identification:

Samples were labeled following removal from packaging with the following identification numbers:

Sample ID #	Lot #	Manufacturer	Description
RF1-RF21, RF32-RF34	07KN2852	C.R. Bard	Recovery Filter
SF1-SF10	07JN2673	C.R. Bard	Simon Nitinol Filter
GT1-GT3	6113410	Boston Scientific	Greenfield (Titanium)
GS1-GS3	6115450	Boston Scientific	Greenfield (Stainless Steel)
GS101-GS103	6201719	Boston Scientific	Greenfield (Stainless Steel)
VT1-VT3, VT101, VT102	F0507080	B-Braun	Vena Tech LP
TP1-TP3	1309079	Cook	Gűnther Tulip
TP4, TP103	1304623	Cook	Gűnther Tulip
O1-O3, O103	R0603592	Cordis	Optease
O102	R0903186	Cordis	Optease
T1-T3	R1103502	Cordis	Trapease

NMT1-NMT10	Unknown	NMT	Recovery Filter

6.0 DEVIATIONS/EXCEPTIONS TO TEST PROTOCOL

The initial testing was run on the test fixture and data sheet as specified in TPR-04-02-02. The testing on this initial fixture was more difficult due to the following:

- The simulated sausage casing clots were getting caught on the rough transitions in the 1" PVC piping.
- The temperature was being captured manually using a digital thermometer which took additional time.
- The transducer display readings were in psi units instead of mmHg.

All data sheets containing data recorded in psi units utilized the initial fixture.

To expedite testing, the data sheet was revised and two new fixtures were manufactured. The following enhancements were made:

- The new fixtures utilized ¾" PVC piping and the piping was reamed to smooth transitions.
- Calibrated transducers with display readings in mmHg were utilized.
- A thermocouple and temperature display was added to reduce testing time.

All data sheets containing data recorded in mmHg units utilized the new fixtures. A photograph of the new fixture is located in appendix 1.

Initial testing utilizing 28mm diameter simulated IVCs was performed at 37°C ± 2°C per protocol; however, the temperature was changed thereafter to 40°C ± 3°C to follow suit with NMT protocol RD-SOP-035.02. The testing in the 28mm diameter simulated IVC was repeated at this new temperature. All subsequent simulated IVC diameters were tested at 40°C ± 3°C in the following order 15mm, 25mm, 21mm, 18mm, 30mm, and 32mm. It is important to note that the filters were all fatigued in this order. As samples broke (i.e. struts), they were replaced with new product.

7.0 TEST RESULTS/SUMMARY OF DATA

The data for the three runs of each filter was averaged before the summary statistics were calculated.

Sample ID	Testing Temp. (°C)	Tube Diameter (mm)	Filter Sample Size (n)	Mean (mmHg)	Standard Deviation (mmHg)	Minimum (mmHg)	Maximum (mmHg)
RF11-RF21	40 ± 3	15	11	151.6	11.28	135.7	177.9
SF1-SF10	40 ± 3	15	10	155.0	0.25	154.3	155.1

Sample ID	Testing Temp. (°C)	Tube Diameter (mm)	Filter Sample Size (n)	Mean (mmHg)	Standard Deviation (mmHg)	Minimum (mmHg)	Maximum (mmHg)
GT1-GT3	40 ± 3	15	3	155.1	0.00	155.1	155.1
GS1-GS3	40 ± 3	15	3	143.8	18.88	122.0	155.1
VT1-VT3	40 ± 3	15	3	155.1	0.00	155.1	155.1
TP1-TP3	40 ± 3	15	3	137.0	6.80	130.3	143.9
O1-O3	40 ± 3	15	3	154.4	0.98	153.3	155.0
T1-T3	40 ± 3	15	3	155.0	0.00	155.0	155.0
RF11-RF20	40 ± 3	18	10	127.3	9.95	111.0	143.9
SF1-SF10	40 ± 3	18	10	152.9	4.00	142.9	155.0
GT1-GT3	40 ± 3	18	3	153.3	1.93	151.2	155.0
GS1-GS3	40 ± 3	18	3	142.0	10.78	129.6	148.8
VT1-VT3	40 ± 3	18	3	121.0	12.34	107.0	130.4
TP2-TP4	40 ± 3	18	3	142.6	11.69	131.8	155.0
O1, O2, O101, O103	40 ± 3	18	4	144.2	14.74	123.8	155.0
T1-T3	40 ± 3	18	3	153.9	1.91	151.7	155.0
RF11-RF20	40 ± 3	21	10	96.1	12.94	83.2	121.6
SF1-SF10	40 ± 3	21	10	150.7	6.89	134.1	155.0
GT1-GT3	40 ± 3	21	3	129.9	19.30	108.2	145.2
GS1-GS3	40 ± 3	21	3	147.8	5.39	143.3	153.8
VT1-VT3	40 ± 3	21	3	131.4	23.11	106.7	152.5
TP2-TP4	40 ± 3	21	3	112.1	15.05	96.1	126.0
O1-O3	40 ± 3	21	3	155.0	0.00	155.0	155.0
T1-T3	40 ± 3	21	3	152.5	4.39	147.4	155.0
RF11-RF21	40 ± 3	25	11	73.9	3.62	66.6	79.9
SF1-SF10	40 ± 3	25	10	116.9	19.06	84.4	149.8
GT1-GT3	40 ± 3	25	3	145.2	15.13	127.8	155.0
GS1-GS3	40 ± 3	25	3	116.6	22.23	91.5	133.7
VT1-VT3	40 ± 3	25	3	107.9	30.86	74.3	135.0
TP1-TP3	40 ± 3	25	3	86.7	10.72	78.3	98.8
O1-O3	40 ± 3	25	3	146.0	3.29	142.5	149.0
T1-T3	40 ± 3	25	3	138.7	2.46	136.6	141.4

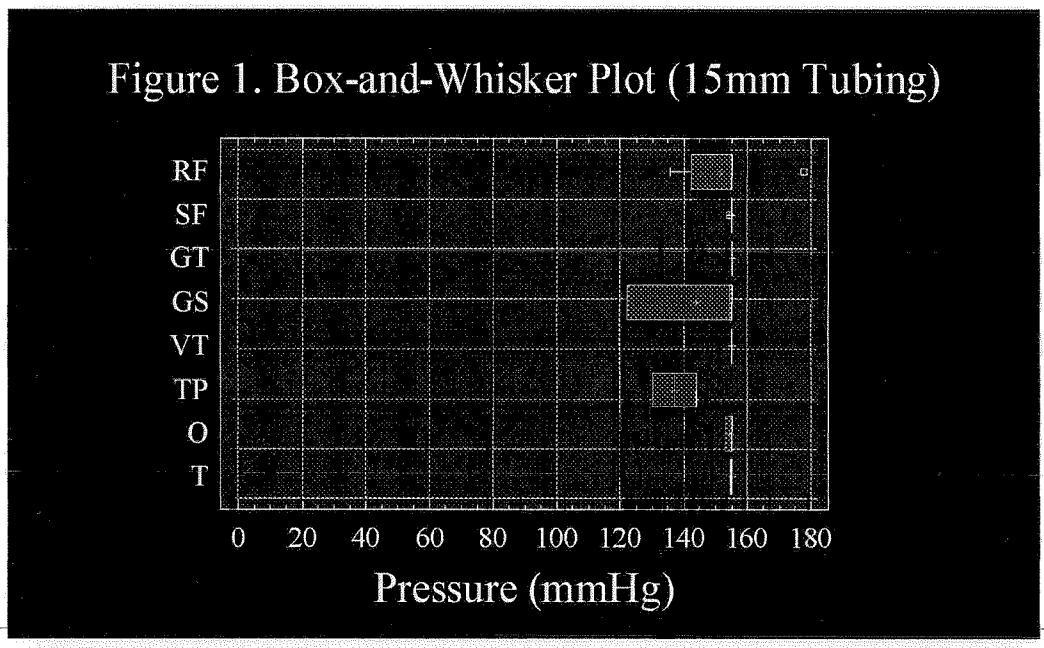
Sample ID	Testing Temp. (°C)	Tube Diameter (mm)	Filter Sample Size (n)	Mean (mmHg)	Standard Deviation (mmHg)	Minimum (mmHg)	Maximum (mmHg)
RF1-RF10, RF32-RF34	37 ± 2	28	13	47.5	9.95	32.1	64.8
SF1-SF10	37 ± 2	28	10	76.3	12.16	65.0	105.8
NMT1-NMT10	40 ± 3	28	10	55.7	5.11	47.1	63.2
RF11-RF21	40 ± 3	28	11	51.3	6.53	43.8	62.9
SF1-SF10	40 ± 3	28	10	89.1	13.23	73.2	108.3
GT1-GT3	40 ± 3	28	3	89.6	6.00	83.2	95.1
GS1-GS3	40 ± 3	28	3	89.9	11.46	83.1	103.1
VT1-VT3	40 ± 3	28	3	76.4	22.79	62.4	102.7
TP1-TP3	40 ± 3	28	3	42.7	9.90	31.7	50.9
O1-O3	40 ± 3	28	3	136.6	7.37	128.1	141.3
T1-T3	40 ± 3	28	3	122.9	21.09	109.0	147.2
RF11-RF20	40 ± 3	30	10	39.6	7.98	26.7	53.8
SF1-SF10	40 ± 3	30	10	92.6	24.02	63.8	138.8
GT1-GT3	40 ± 3	30	3	78.4	23.26	57.1	103.2
GS1-GS3, GS101-GS103	40 ± 3	30	3	102.5	4.10	98.3	106.5
VT1, VT3, VT101, VT102	40 ± 3	30	4	74.9	17.93	51.1	93.4
TP3, TP4, TP101-TP103	40 ± 3	30	5	55.8	19.87	26.9	82.7
O1, O2, O102, 0103	40 ± 3	30	4	103.3	12.36	85.3	112.4
T1-T3	40 ± 3	30	3	96.3	12.46	84.2	109.1
RF11-RF20	40 ± 3	32	10	34.6	5.43	25.8	43.2
SF1-SF10	40 ± 3	32	10	79.4	15.76	56.5	112.7
GT1-GT3	40 ± 3	32	3	90.2	14.36	74.1	101.7
GS1-GS3, GS101, GS103	40 ± 3	32	6	68.7	26.48	24.6	101.0
VT1, VT101, VT102	40 ± 3	32	3	58.9	16.83	47.5	78.2
TP4, TP101-TP103	40 ± 3	32	4	35.8	13.41	19.7	50.0
O2, O102, Q103	40 ± 3	32	3	86.2	10.12	74.6	93.2
T1-T3	40 ± 3	32	3	73.6	10.74	63.8	85.1

NOTE: Reference appendix 2 for Statgraphics Plus[1] summary statistics, appendix 3 tabulated Excel[2] data/calculated averages for each filter, and appendices 4-10 for raw data.

[1] Statgraphics Plus is a registered trademark of Manugistics, Inc.
[2] Excel is a registered trademark of Microsoft, Inc.

8.0 ANALYSIS OF DATA

8.1 Box-and-Whisker plots were generated to compare filter product for each simulated IVC diameter tube.



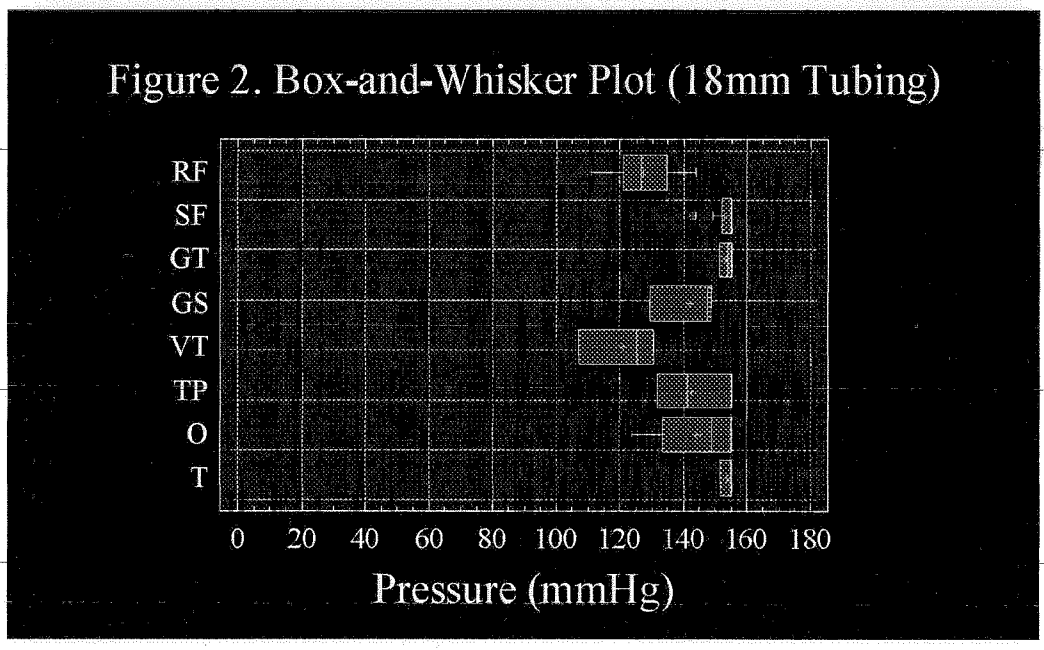


Figure 3. Box-and-Whisker Plot (21mm Tubing)

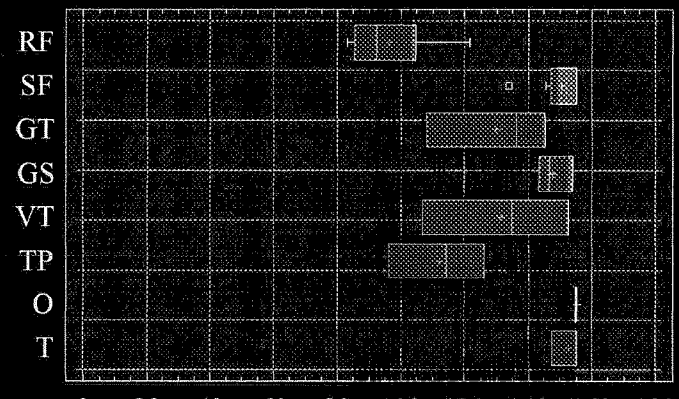


Figure 4. Box-and-Whisker Plot (25mm Tubing)

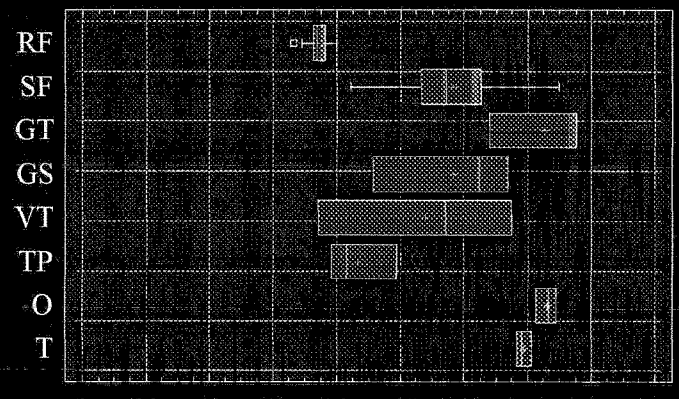


Figure 5. Box-and-Whisker Plot (28mm Tubing)

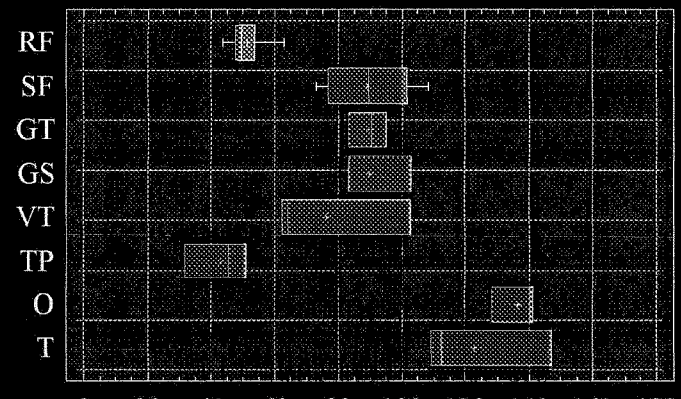
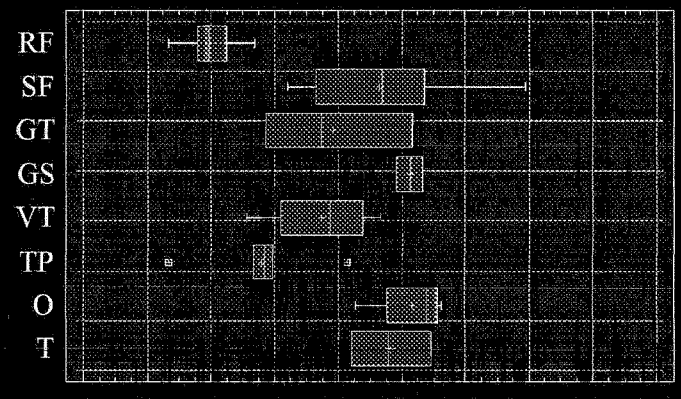
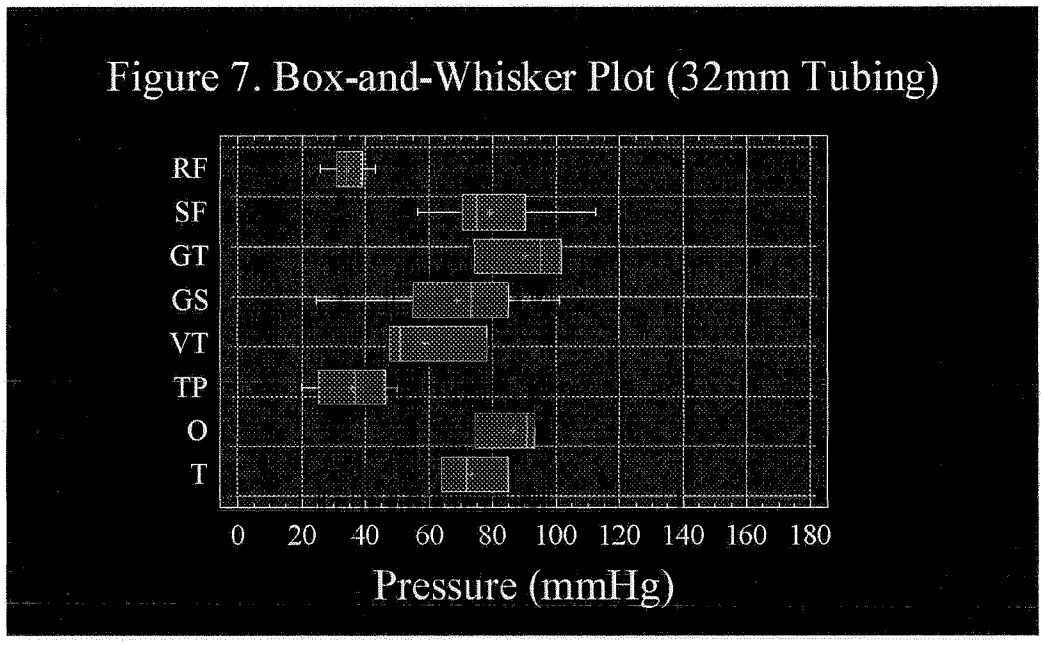
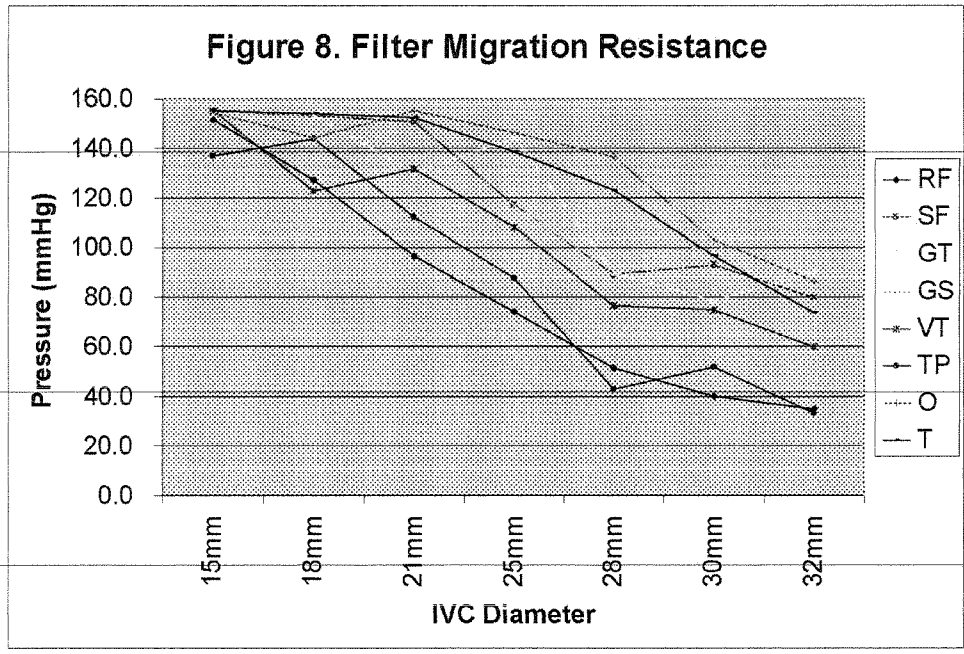


Figure 6. Box-and-Whisker Plot (30mm Tubing)





8.2 A summary graph was generated utilizing the average of each filter type for each diameter for comparative purposes.



9.0 DISCUSSION OF RESULTS

Due to the small sample sizes of competitive product tested for migration resistance, statistical comparisons were not made. However, by looking at the plots in section 8 it appears as if the Recovery and Gűnther Tulip Filters are comparable in regards to filter migration. All other competitive filters appear to have a higher migration resistance.

It is important to note that there was a large amount of test variation. In a follow-up report, ETR-04-03-05, it was determined that the variation could be minimized by the following:

- Introduce one simulated clot at a time.
- Invert the sausage casing upon itself to create two layers and position the fold on the bottom of the simulated IVC where the casing is attached to the PVC piping.

The Recovery Filter was retested in the 28mm diameter simulated IVC to compare to historic NMT data utilizing the changes to decrease variation. It is important to note that the mean value increased and the standard deviation decreased.

Another study would have to be performed to determine the true statistical migration resistance differences or equivalencies between competitive filters.

10.0 CONCLUSION

The migration resistance of the Recovery Filter appears comparable to the Gűnther Tulip Filter throughout all simulated IVC diameters. The other filters seem to have a greater resistance to migration in comparison to the Recovery Filter and Gűnther Tulip Filter.

11.0 APPENDICIES

1. New Flow Loop Migration Test Fixture
2. Statgraphic Summary Statistics
3. Excel Tabulated Data/Calculated Average for Each Filter
4. 15mm Diameter Simulated IVC Raw Data
5. 18mm Diameter Simulated IVC Raw Data
6. 21mm Diameter Simulated IVC Raw Data
7. 25mm Diameter Simulated IVC Raw Data
8. 28mm Diameter Simulated IVC Raw Data
9. 30mm Diameter Simulated IVC Raw Data
10. 32mm Diameter Simulated IVC Raw Data
11. Filter Migration Digital Video Tapes

Appendix 1 New Flow Loop Migration Test Fixture

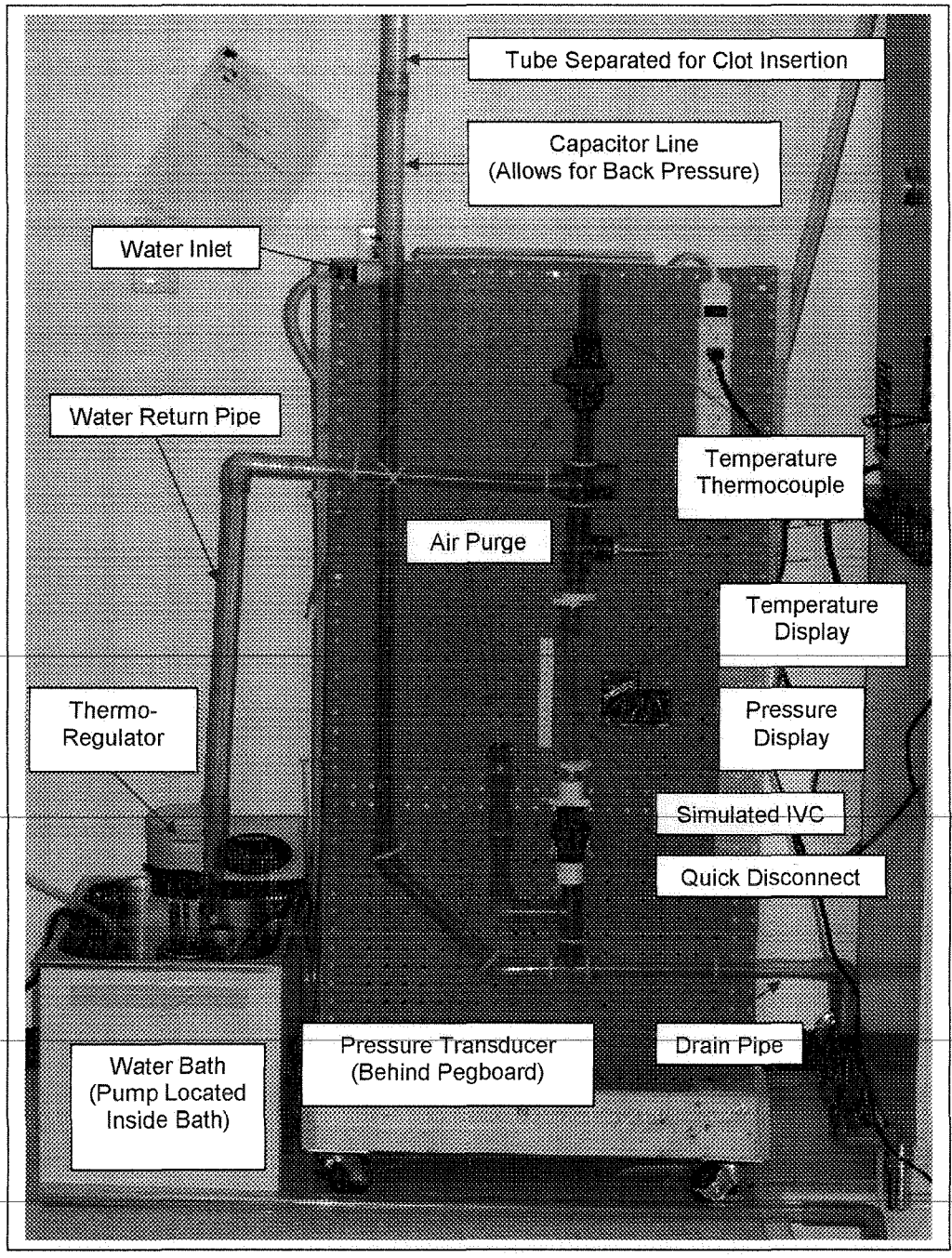


EXHIBIT 32

From: Tessmer, Alex [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=ATESSMER]
Date: 3/24/2004 11:34:55 PM
To: Benware, Charlie [Charlie.Benware@crbard.com], Fitzpatrick, Ed [Ed.Fitzpatrick@crbard.com]
CC: Hudson, Brian [Brian.Hudson@crbard.com], Carr, Robert [Robert.Carr@crbard.com]
Subject: Starguide Filter Migration Test Results
Attachments: Starguide.xls

Charlie and Ed,

I have shipped copies of the migration resistance test data sheets via FEDEX overnight (tracking #6347 6318 7941). I have also attached an Excel spreadsheet with the raw data results and along with an average result for each filter.

A total quantity of 40 filters were tested. Each filter was tested three times for a total of 120 runs.

A quantity of 10 filters from each of the three ESM lots were tested (n=30 Starguide nitinol wire). A quantity of 10 filters manufactured using the current supplier wire were also tested.

You will quickly notice that there were values below the 50.0 mmHg acceptance criteria for all the three Starguide manufactured lots. Since this was the case, we tested filters manufactured using the current supplier wire to determine whether the issue was with the filters or the migration resistance testing. We quickly discovered that there were values below 50.0 mmHg when testing the filters manufactured using the current supplier. This points to the fact that there is an issue with the migration resistance testing.

When we had previously tested the GFO manufactured filters to compare to historic NMT data, all data values were above the 50.0 mmHg acceptance criteria. The testing that was performed on the filters above utilized an identical test method. It is important to note that a new batch of sausage casing had been purchased to complete the testing. However, the operators did not notice any difference with the new casing in comparison to what had been previously used. The sausage casing was packaged the same and came from the same supplier. It had the same appearance, feel, and odor as the previous casing.

In any case, more testing may need to occur before the Starguide nitinol wire should be approved. Perhaps we can test the radial expasion force of 10 Starguide manufactured filters to determine if the data is statiscally equivalent to the data we captured for the filters manufactured using the current nitinol supplied wire. Please contact Brian Hudson to discuss this issue further.

Best regards,

Alex

Alex Tessmer
Bard Peripheral Vascular
Research & Development
Engineer II
1415 West 3rd Street, Suite 109
Tempe, AZ 85281
Direct: 480-303-2704
FAX: 480-449-2597
Email: alex.tessmer@crbard.com

EXHIBIT 33

BARD PERIPHERAL VASCULAR

Engineering Test Report Number

ETR-04-03-02
REV 0

Characterization of Recovery Filter Migration Resistance in Comparison to Competitive Product
Phase 1

1.0 OBJECTIVE / PURPOSE OF TEST

The objective of this study was to compare the Recovery Filter (RF) to competitive products in relationship to migration resistance.

2.0 INTRODUCTION / BACKGROUND INFORMATION

The design of the Recovery Filter was originally challenged for migration resistance capabilities by Nitinol Medical Technologies (NMT), the original design facility. The results of NMT's testing indicated that both the Simon Nitinol Filter and RF products were able to resist migration at the minimum pressure of 50 mmHg (predefined acceptance criteria) in 15 and 28mm diameter mock vessels (ref. 3.3 and 3.4).

Recent field activities indicate that migration failures have been reported for the RF product. Therefore, further testing of this specific characteristic is warranted.

In conjunction with the field activities, a special Design Review was held on December 5th of 2003 to gain a further understanding of the design elements of this product. In preparation for the special Design Review, the DFMEA for Recovery Filter was analyzed for critical elements to be discussed during the review (ref. 3.1). Migration resistance was one of the critical elements identified for review. The outcome from this special Design Review was a list of action items, many of which were related to migration resistance (ref. 3.2). One of the migration resistance action items is being addressed in this report.

3.0 REFERENCE DOCUMENTS

3.1 Memorandum entitled "Design Review Objectives for Recovery FMR launch (Project #'s 7081 and 8008)", dated December 4th, 2003.
3.2 Memorandum entitled "Special Design Review for Recovery (Project #'s 7081 and 8008) Meeting Minutes", dated December 9th, 2003.
3.3 RF Migration Study, Design Verification (RD-RPT-100)
3.4 IVC Filter Migration Study (RD-SOP-035.02)

4.0 TEST PROCEDURE

Test protocol TPR-04-02-02 was followed with the deviations as noted in section 6.0. The phase 1 portion of testing is summarized in this report. The phase 1 testing included testing migration resistance of the following products: Bard Recovery Filter, Bard Simon Nitinol Filter, Boston Scientific Greenfield Stainless Steel, Boston Scientific Greenfield Titanium, B-Braun Vena Tech, Cook Günther Tulip, Cordis TrapEase, and Cordis OptEase. The filters were tested in the following simulated IVC diameters: 15mm, 18mm, 21mm, 25mm, 28mm, 30mm, and 32mm.

5.0 TEST MATERIALS

5.1 Number of Samples:

A minimum of 38 samples were evaluated as part of this study.

5.2 Sample Size/Sample Grouping Rationale:

The following samples sizes and groups were identified as test samples:

Qty.	Manufacturer	Description
10	C.R. Bard	Recovery Filter
10	C.R. Bard	Simon Nitinol Filter
3	Boston Scientific	Greenfield (Titanium)
3	Boston Scientific	Greenfield (Stainless Steel)
3	B-Braun	Vena Tech LP
3	Cook	Gűnther Tulip
3	Cordis	OptEase
3	Cordis	TrapEase
10	NMT	Recovery Filter (Tested only in 28mm tubing)

It became necessary to replace filters when struts and major deformation occurred. New samples were given IDs in subsequent order. In some cases, the sample size increased.

5.3 Sample Identification:

Samples were labeled following removal from packaging with the following identification numbers:

Sample ID #	Lot #	Manufacturer	Description
RF1-RF21, RF32-RF34	07KN2852	C.R. Bard	Recovery Filter
SF1-SF10	07JN2673	C.R. Bard	Simon Nitinol Filter
GT1-GT3	6113410	Boston Scientific	Greenfield (Titanium)
GS1-GS3	6115450	Boston Scientific	Greenfield (Stainless Steel)
GS101-GS103	6201719	Boston Scientific	Greenfield (Stainless Steel)
VT1-VT3, VT101, VT102	F0507080	B-Braun	Vena Tech LP
TP1-TP3	1309079	Cook	Gűnther Tulip
TP4, TP103	1304623	Cook	Gűnther Tulip
O1-O3, O103	R0603592	Cordis	Optease
O102	R0903186	Cordis	Optease
T1-T3	R1103502	Cordis	Trapease
NMT1-NMT10	Unknown	NMT	Recovery Filter

6.0 DEVIATIONS/EXCEPTIONS TO TEST PROTOCOL

The initial testing was run on the test fixture and data sheet as specified in TPR-04-02-02. The testing on this initial fixture was more difficult due to the following:

- The simulated sausage casing clots were getting caught on the rough transitions in the 1" PVC piping.
- The temperature was being captured manually using a digital thermometer which took additional time.
- The transducer display readings were in psi units instead of mmHg.

All data sheets containing data recorded in psi units utilized the initial fixture.

To expedite testing, the data sheet was revised and two new fixtures were manufactured. The following enhancements were made:

- The new fixtures utilized ¾" PVC piping and the piping was reamed to smooth transitions.
- Calibrated transducers with display readings in mmHg were utilized.
- A thermocouple and temperature display was added to reduce testing time.

All data sheets containing data recorded in mmHg units utilized the new fixtures. A photograph of the new fixture is located in appendix 1.

Initial testing utilizing 28mm diameter simulated IVCs was performed at 37°C ± 2°C per protocol; however, the temperature was changed thereafter to 40°C ± 3°C to follow suit with NMT protocol RD-SOP-035.02. The testing in the 28mm diameter simulated IVC was repeated at this new temperature. All subsequent simulated IVC diameters were tested at 40°C ± 3°C in the following order 15mm, 25mm, 21mm, 18mm, 30mm, and 32mm. It is important to note that the filters were all fatigued in this order. As samples broke (i.e. struts), they were replaced with new product.

7.0 TEST RESULTS/SUMMARY OF DATA

The data for the three runs of each filter was averaged before the summary statistics were calculated.

Sample ID	Testing Temp. (°C)	Tube Diameter (mm)	Filter Sample Size (n)	Mean (mmHg)	Standard Deviation (mmHg)	Minimum (mmHg)	Maximum (mmHg)
RF11-RF21	40 ± 3	15	11	151.6	11.28	135.7	177.9
SF1-SF10	40 ± 3	15	10	155.0	0.25	154.3	155.1
GT1-GT3	40 ± 3	15	3	155.1	0.00	155.1	155.1
GS1-GS3	40 ± 3	15	3	143.8	18.88	122.0	155.1

Sample ID	Testing Temp. (°C)	Tube Diameter (mm)	Filter Sample Size (n)	Mean (mmHg)	Standard Deviation (mmHg)	Minimum (mmHg)	Maximum (mmHg)
VT1-VT3	40 ± 3	15	3	155.1	0.00	155.1	155.1
TP1-TP3	40 ± 3	15	3	137.0	6.80	130.3	143.9
O1-O3	40 ± 3	15	3	154.4	0.98	153.3	155.0
T1-T3	40 ± 3	15	3	155.0	0.00	155.0	155.0
RF11-RF20	40 ± 3	18	10	127.3	9.95	111.0	143.9
SF1-SF10	40 ± 3	18	10	152.9	4.00	142.9	155.0
GT1-GT3	40 ± 3	18	3	153.3	1.93	151.2	155.0
GS1-GS3	40 ± 3	18	3	142.0	10.78	129.6	148.8
VT1-VT3	40 ± 3	18	3	121.0	12.34	107.0	130.4
TP2-TP4	40 ± 3	18	3	142.6	11.69	131.8	155.0
O1, O2, O101, O103	40 ± 3	18	4	144.2	14.74	123.8	155.0
T1-T3	40 ± 3	18	3	153.9	1.91	151.7	155.0
RF11-RF20	40 ± 3	21	10	96.1	12.94	83.2	121.6
SF1-SF10	40 ± 3	21	10	150.7	6.89	134.1	155.0
GT1-GT3	40 ± 3	21	3	129.9	19.30	108.2	145.2
GS1-GS3	40 ± 3	21	3	147.8	5.39	143.3	153.8
VT1-VT3	40 ± 3	21	3	131.4	23.11	106.7	152.5
TP2-TP4	40 ± 3	21	3	112.1	15.05	96.1	126.0
O1-O3	40 ± 3	21	3	155.0	0.00	155.0	155.0
T1-T3	40 ± 3	21	3	152.5	4.39	147.4	155.0
RF11-RF21	40 ± 3	25	11	73.9	3.62	66.6	79.9
SF1-SF10	40 ± 3	25	10	116.9	19.06	84.4	149.8
GT1-GT3	40 ± 3	25	3	145.2	15.13	127.8	155.0
GS1-GS3	40 ± 3	25	3	116.6	22.23	91.5	133.7
VT1-VT3	40 ± 3	25	3	107.9	30.86	74.3	135.0
TP1-TP3	40 ± 3	25	3	86.7	10.72	78.3	98.8
O1-O3	40 ± 3	25	3	146.0	3.29	142.5	149.0
T1-T3	40 ± 3	25	3	138.7	2.46	136.6	141.4
RF1-RF10, RF32-RF34	37 ± 2	28	13	47.5	9.95	32.1	64.8
SF1-SF10	37 ± 2	28	10	76.3	12.16	65.0	105.8

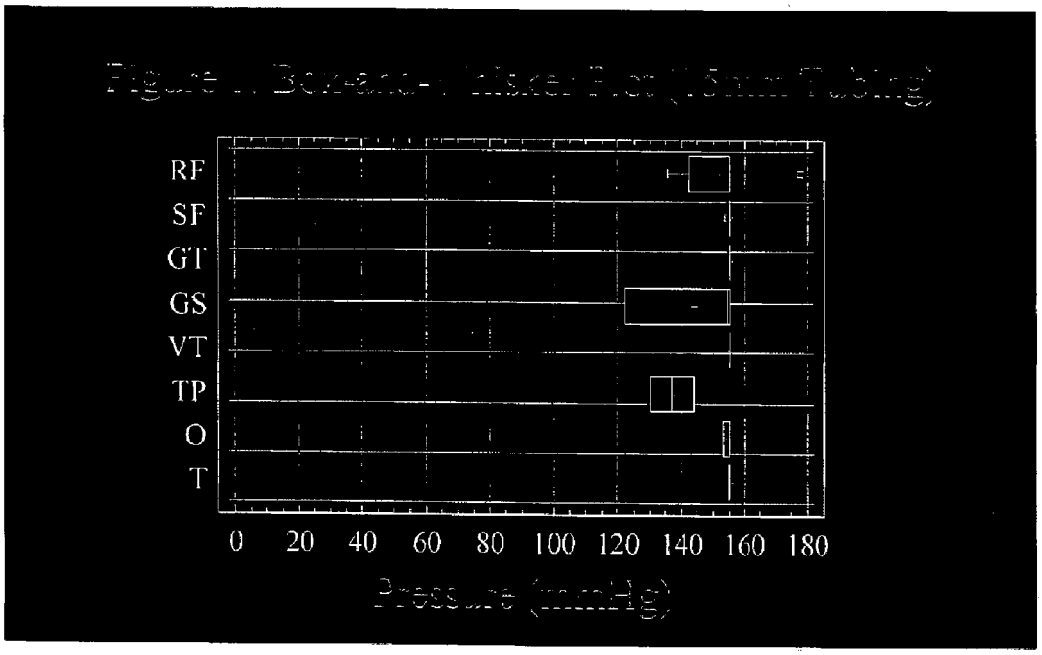
Sample ID	Testing Temp. (°C)	Tube Diameter (mm)	Filter Sample Size (n)	Mean (mmHg)	Standard Deviation (mmHg)	Minimum (mmHg)	Maximum (mmHg)
NMT1-NMT10	40 ± 3	28	10	55.7	5.11	47.1	63.2
RF11-RF21	40 ± 3	28	11	51.3	6.53	43.8	62.9
SF1-SF10	40 ± 3	28	10	89.1	13.23	73.2	108.3
GT1-GT3	40 ± 3	28	3	89.6	6.00	83.2	95.1
GS1-GS3	40 ± 3	28	3	89.9	11.46	83.1	103.1
VT1-VT3	40 ± 3	28	3	76.4	22.79	62.4	102.7
TP1-TP3	40 ± 3	28	3	42.7	9.90	31.7	50.9
O1-O3	40 ± 3	28	3	136.6	7.37	128.1	141.3
T1-T3	40 ± 3	28	3	122.9	21.09	109.0	147.2
RF11-RF20	40 ± 3	30	10	39.6	7.98	26.7	53.8
SF1-SF10	40 ± 3	30	10	92.6	24.02	63.8	138.8
GT1-GT3	40 ± 3	30	3	78.4	23.26	57.1	103.2
GS1-GS3, GS101-GS103	40 ± 3	30	3	102.5	4.10	98.3	106.5
VT1, VT3, VT101, VT102	40 ± 3	30	4	74.9	17.93	51.1	93.4
TP3, TP4, TP101-TP103	40 ± 3	30	5	55.8	19.87	26.9	82.7
O1, O2, O102, 0103	40 ± 3	30	4	103.3	12.36	85.3	112.4
T1-T3	40 ± 3	30	3	96.3	12.46	84.2	109.1
RF11-RF20	40 ± 3	32	10	34.6	5.43	25.8	43.2
SF1-SF10	40 ± 3	32	10	79.4	15.76	56.5	112.7
GT1-GT3	40 ± 3	32	3	90.2	14.36	74.1	101.7
GS1-GS3, GS101, GS103	40 ± 3	32	6	68.7	26.48	24.6	101.0
VT1, VT101, VT102	40 ± 3	32	3	58.9	16.83	47.5	78.2
TP4, TP101-TP103	40 ± 3	32	4	35.8	13.41	19.7	50.0
O2, O102, Q103	40 ± 3	32	3	86.2	10.12	74.6	93.2
T1-T3	40 ± 3	32	3	73.6	10.74	63.8	85.1

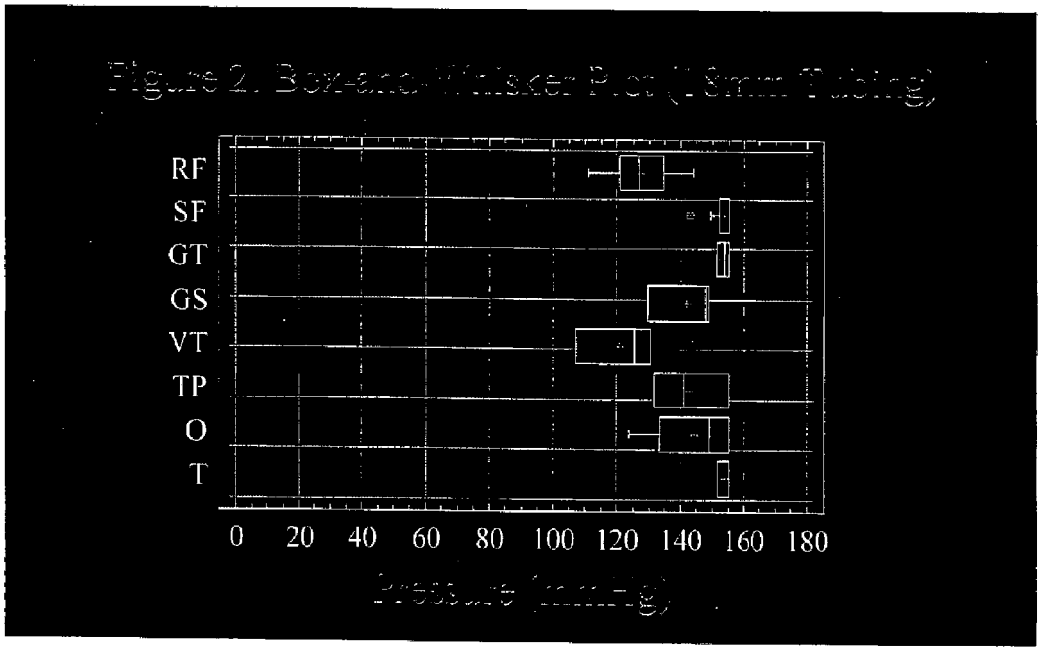
NOTE: Reference appendix 2 for Statgraphics Plus[1] summary statistics, appendix 3 tabulated Excel[2] data/calculated averages for each filter, and appendices 4-10 for raw data.

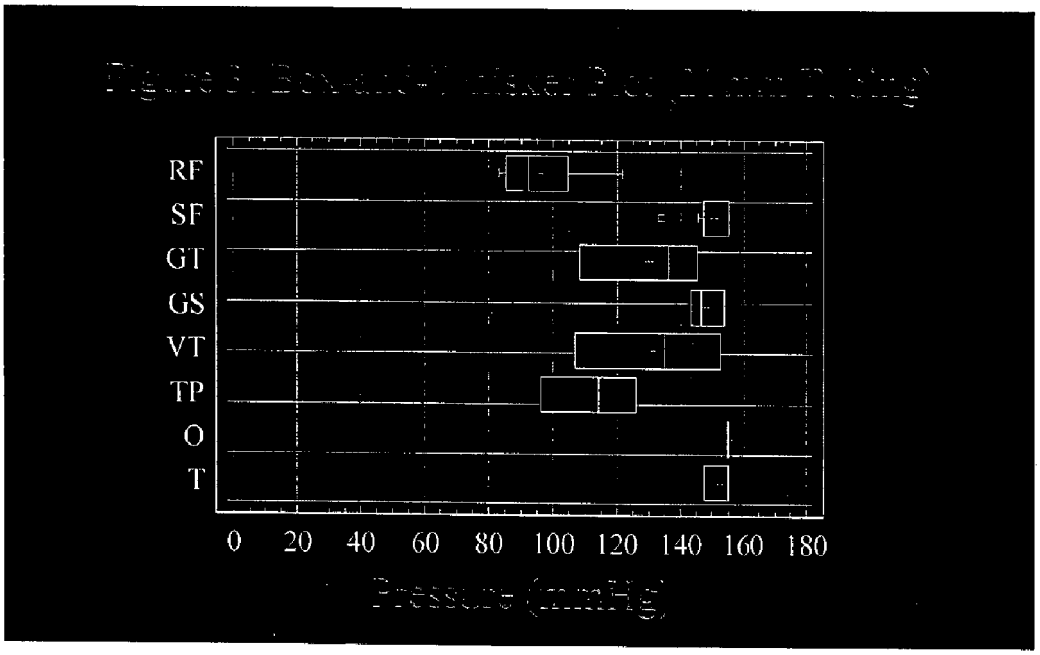
[1] Statgraphics Plus is a registered trademark of Manugistics, Inc.
[2] Excel is a registered trademark of Microsoft, Inc.

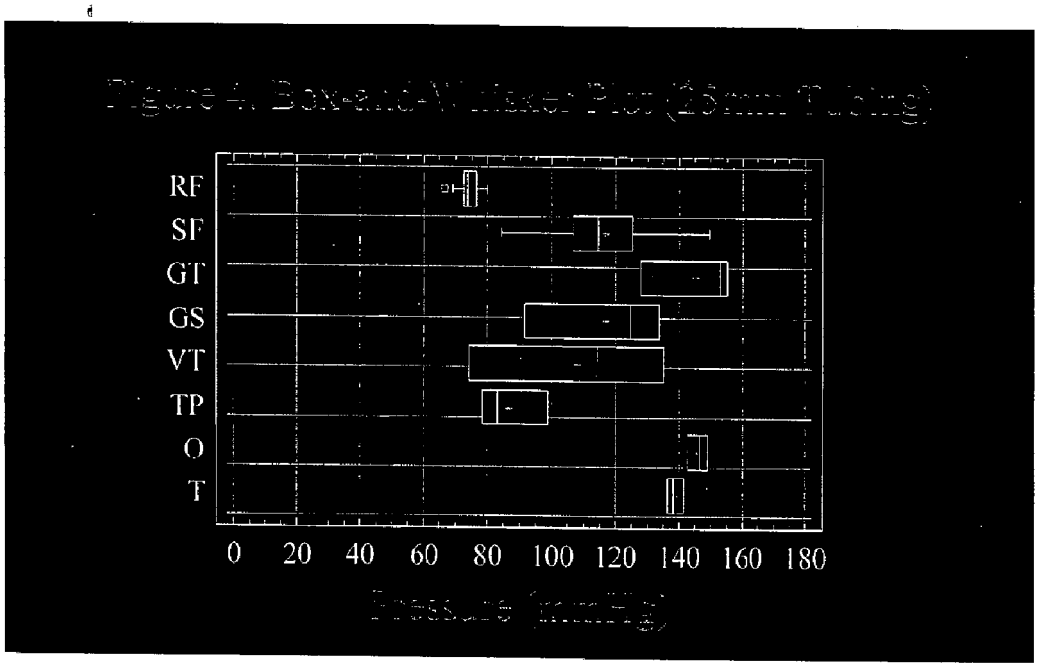
8.0 ANALYSIS OF DATA

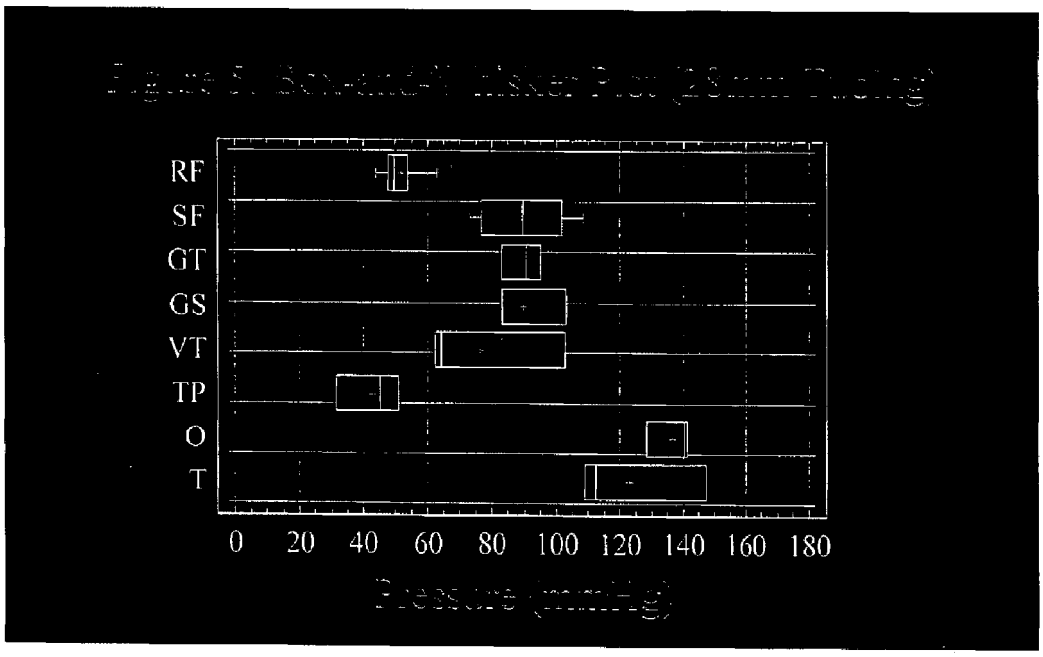
8.1 Box-and-Whisker plots were generated to compare filter product for each simulated IVC diameter tube.

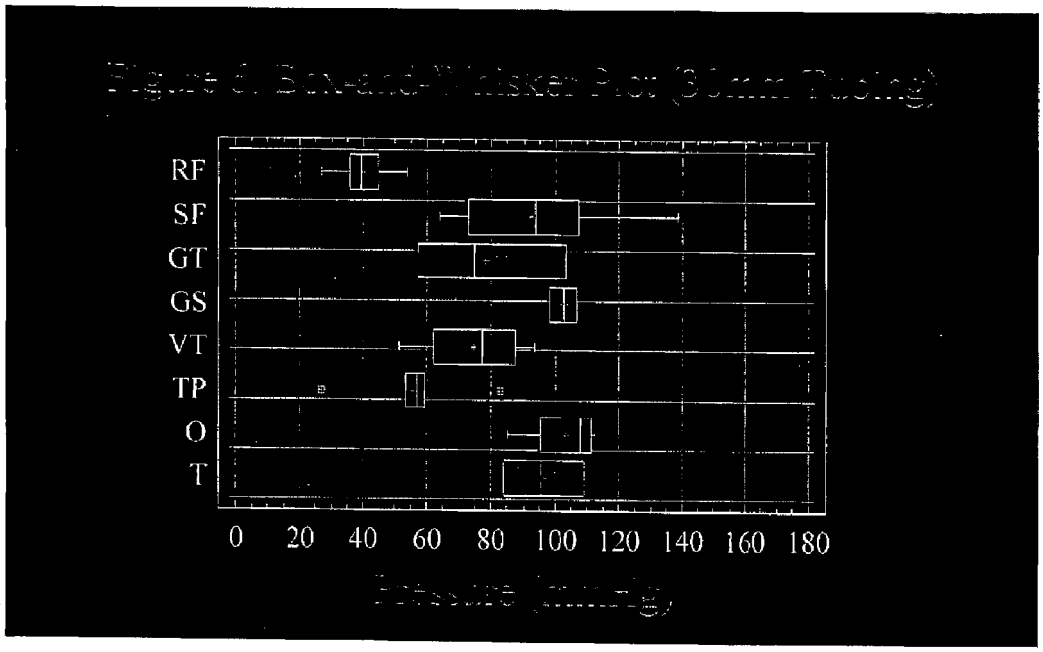


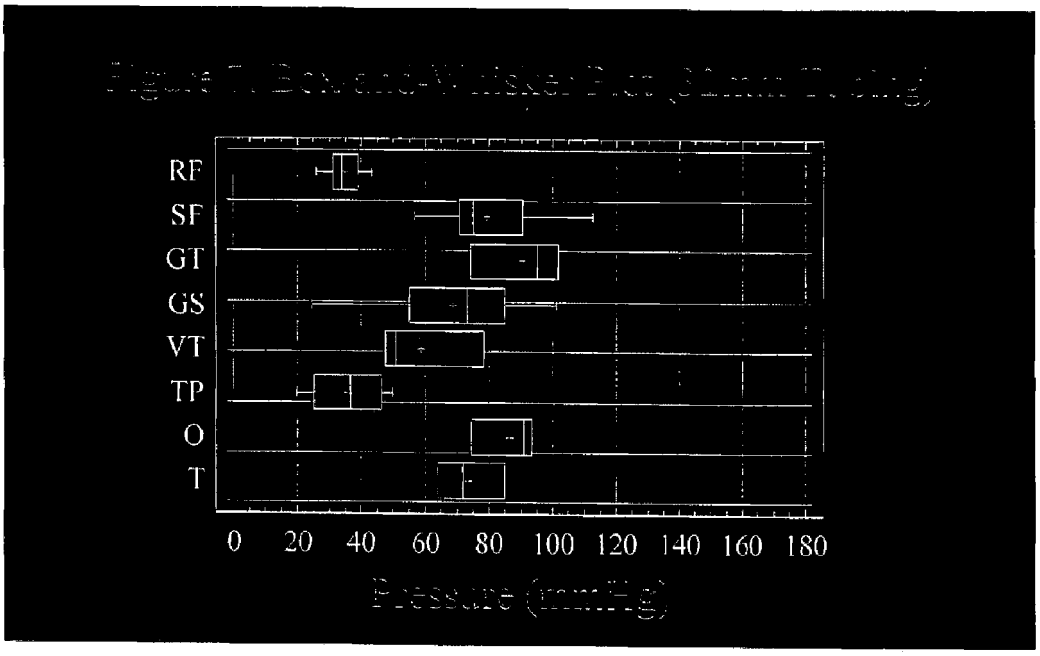




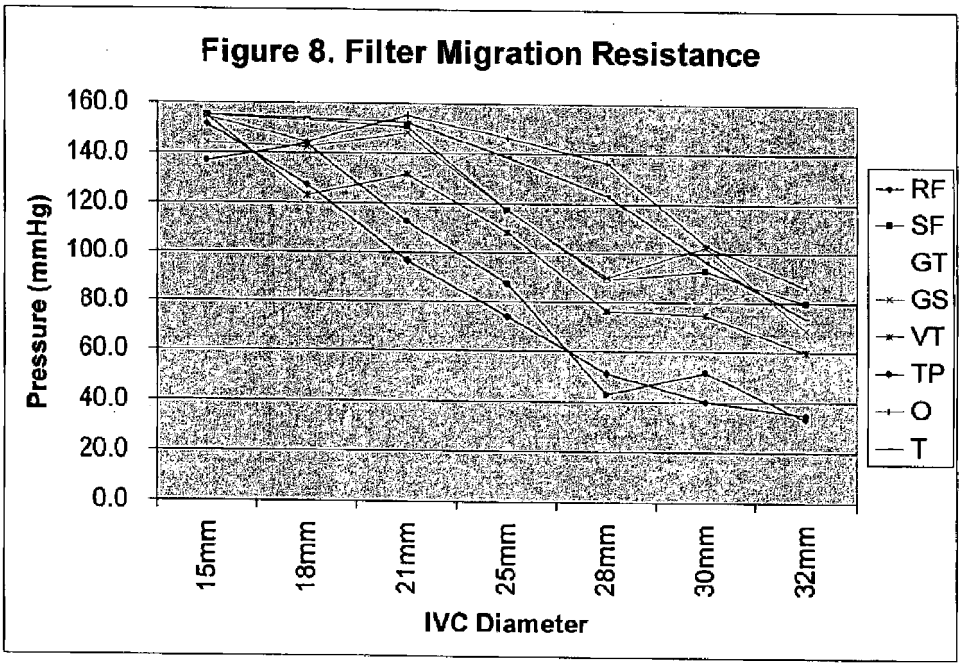








8.2 A summary graph was generated utilizing the average of each filter type for each diameter for comparative purposes.



9.0 DISCUSSION OF RESULTS

Due to the small sample sizes of competitive product tested for migration resistance, statistical comparisons were not made. However, by looking at the plots in section 8 it appears as if the Recovery and Gűnther Tulip Filters are comparable in regards to filter migration. All other competitive filters appear to have a higher migration resistance.

It is important to note that there was a large amount of test variation. In a follow-up report, ETR-04-03-05, it was determined that the variation could be minimized by the following:

- Introduce one simulated clot at a time.
- Invert the sausage casing upon itself to create two layers and position the fold on the bottom of the simulated IVC where the casing is attached to the PVC piping.

The Recovery Filter was retested in the 28mm diameter simulated IVC to compare to historic NMT data utilizing the changes to decrease variation. It is important to note that the mean value increased and the standard deviation decreased.

Another study would have to be performed to determine the true statistical migration resistance differences or equivalencies between competitive filters.

10.0 CONCLUSION

The migration resistance of the Recovery Filter appears comparable to the Gűnther Tulip Filter throughout all simulated IVC diameters. The other filters seem to have a greater resistance to migration in comparison to the Recovery Filter and Gűnther Tulip Filter.

11.0 APPENDICIES

1. New Flow Loop Migration Test Fixture
2. Statgraphic Summary Statistics
3. Excel Tabulated Data/Calculated Average for Each Filter
4. 15mm Diameter Simulated IVC Raw Data
5. 18mm Diameter Simulated IVC Raw Data
6. 21mm Diameter Simulated IVC Raw Data
7. 25mm Diameter Simulated IVC Raw Data
8. 28mm Diameter Simulated IVC Raw Data
9. 30mm Diameter Simulated IVC Raw Data
10. 32mm Diameter Simulated IVC Raw Data
11. Filter Migration Digital Video Tapes

EXHIBIT 35

Health Hazard Evaluation

DATE: December 17, 2004

TO: Doug Uelmen, BPV QA

FROM: David Ciavarella, M.D.

RE: Recovery® Filter – Consultant's report

Summary: Seventy-six reports of potentially serious hazards have been reported; 32 of these were judged to be serious, and 10 reports were associated with patient death. Total Recovery filter sales during this reporting period (through December 13, 2004) are 20,827 units. Reporting rates of death and other potentially serious complications for the Recovery filter remain below those reported in the literature. However, literature data are not directly comparable to these reporting rates. An analysis of reporting rates of serious adverse events for all inferior vena cava filters, as determined by analysis of the MAUDE and IMS databases by a consultant, revealed that reporting rates for Recovery are significantly higher than other filters. However, these databases are subject to known, significant biases that make calculation or comparison of incidence rates among products unreliable and inadvisable (according to experts and the FDA). Nevertheless, the number of reported complaints, and the size of the differences between Recovery and other filters, warrant further investigation.
Conclusion: The Frequency category for serious injury (Critical Severity rating) is Occasional (32/20,827, or 0.153%). The Frequency category for non-serious injury (Marginal Severity rating) is Occasional (44/20,827, or 0.21%).

Description of the Problem: Based on awareness of reports of patient death associated with migration of the Recovery inferior vena cava (IVC) filter, Bard requested an independent study of the risks and benefits of the Recovery filter, with an emphasis on its use in bariatric surgery and trauma patients. A consultant was retained for this purpose. The consultant's assignment had three components: 1) Perform a literature review of the risks and benefits of IVC filters, with an emphasis on bariatric surgery and trauma patients; 2) Review internal complaint files for the Recovery filter, and compare its reported adverse events rates to those of competitors' IVC filter by use of the MAUDE and IMS (sales) databases or other means; & 3) develop options for clinical studies that might provide information required to assess the risks and benefits of use of the Recovery filter.

The consultant made the following points:

1) The existing literature is of poor quality, with insufficient randomized, controlled trials (RCT) to definitively establish the effectiveness of IVC filters. However, widespread consensus exists in the medical community, obtained via clinical studies of lower credibility than the RCT (such as case reports, case series and prospective non-randomized studies of small size) and expert opinion, that IVC filters lower the likelihood of death from pulmonary embolus in patient groups thought to be at highest risk of this manifestation of venous thromboembolic disease. These high risk groups include patients who have already had a pulmonary embolus or in whom standard anticoagulation therapy cannot be given. However, the existing literature contains comparatively little information on a new generation of IVC filters, especially those with a removability feature (Recovery, Cook Tulip™ and Cordis OptEase™).

   Proper product comparisons can be only be drawn from clinical studies where patient populations are carefully defined, comparisons are made under controlled circumstances from equivalent pa-

tient groups, and adverse events are prospectively defined and sought for in an effective manner. Such studies do not exist for the Recovery filter or its competitors. Therefore, the consultant judged that the literature is an inadequate source of reliable information upon which to make a risk/benefit assessment for the Recovery filter, either alone or in comparison to other IVC filters.

2) The consultant's analysis of the reports to Bard of adverse events associated with Recovery, along with competitors' information available via the MAUDE and IMS databases, showed the following:
    a. Reports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rates for all other filters. These differences were all statistically significant. Recovery's reporting rates for all adverse events, filter fracture, filter migration, and filter migration deaths were found to be significantly higher than those for other removable filters. The TrapEase filter was found to have a statistically significant increased reporting rate for IVC thrombosis when compared to reporting rates for other filters.

    b. These reported adverse event rates were analyzed in conjunction with a bench test performed at BPV. This test measured "migration resistance" in a simulated IVC. Recovery filter had the lowest mean migration resistance (50 mm Hg), just below that of the removable Tulip filter (55 mm Hg). Linear regression analysis showed a significant inverse correlation (R^2 values of 0.40 to 0.65) of reported migration rates to the migration resistance values in the bench test.

    c. An analysis of the quality and validity of this analytical approach (use of MAUDE and IMS databases to generate comparative event rates), however, was performed as well. Many references were found that discussed the inadvisability of using MAUDE data for this purpose. Reported event data are seriously flawed, due to underreporting, various acknowledged forms of bias (such as the known propensity for more reports of adverse events in newer products), and confounding effects (such as lack of comparability in patient groups). The FDA has stated that such an approach is "…problematic, if not completely biased" [1] and "Accumulated reports cannot be used to calculate incidence or to estimate drug risk. Comparisons between drugs cannot be made from these data.". [2] Similar biases were discussed for use of the IMS sales data, in particular, the known lag period that exists between data collection and data publication, leading to large biases in data for products that are new or where indications are in evolution. Thus, actual incidence rates cannot be determined by this approach; these data are better interpreted as providing a signal for further investigation.

    d. A risk/benefit assessment has not been done, because the potential unique benefits of the Recovery filter (e.g., in certain patient groups) have not been evaluated as part of the consultant's report.

3) Little formal analysis has been completed with respect to potential clinical trials to obtain more definitive risk/benefit information. A randomized, controlled trial is the gold standard for determining risks and benefits; however, such a study is likely to require many subjects and therefore be difficult or impossible to execute. The consultant stated that a survey of physicians regarding their use of IVC filters and/or an analysis of data from a large payor or provider organization might be alternative approaches that might provide useful information in a shorter timeframe.

In addition to the consultant's report, a case-by-case analysis of all reported Recovery complaints as of December 13, 2004 related to filter migration, filter fracture, IVC thrombosis, IVC perforation and recurrent pulmonary embolus was performed.

The Actual Occurrence of Injuries: Serious injury is defined here as reported death, or necessity for a surgical intervention to prevent death or serious injury. Reported recurrent pulmonary embolus or IVC thrombosis despite the presence of the filter were also classified as serious injury. In addition, migration of a filter or filter fragments to the heart or lung, or the presence of a filter fragment outside the vasculature, were classified as serious injury, since there is a possibility that serious injury could develop in the future.

With these criteria, there were a total of 32 reported serious injuries, a reporting rate of 0.153%. Details of these reports are given below.

Human Exposure to the Problem: About 20,827 Recovery filters have been distributed as of December 13, 2004.

General Consequences: The consequences of reported adverse events associated with the Recovery IVC filter depend upon the kind of event. Filter migration to the heart, especially when the filter is encased in thrombus, has been associated with sudden death. In some cases, filter migration is associated with trapping of clot before it reaches the heart, and it continues to perform its primary function despite the migration. Filter fracture may be asymptomatic, but has been associated with fragment embolization to the heart causing syncope and/or arrhythmias. IVC perforation is also generally asymptomatic, but it can lead to serious bleeding and, if occurring in conjunction with filter limb fracture, may be associated with fragment migration outside the IVC to nearby organs.

Population Exposed to the Risk: All patients in whom a Recovery filter is placed are potentially at risk for filter-associated adverse events.

Mitigating/Predisposing Factors in the Population at Risk: Unknown.

Nature & Seriousness of the Risk: The nature of the injury is generally related to the cardiovascular system, such as pulmonary embolus, myocardial or pericardial puncture or damage, or bleeding. There was one case of renal vein thrombosis requiring dialysis, listed as a serious event because the filter migrated above the renal veins, thus potentially allowing clot in the lower IVC to propagate to the renal veins. However, it is also possible that renal vein thrombosis developed because of the underlying disease and was unrelated to the filter migration. There was one case of reported IVC thrombosis in a patient in whom recurrent pulmonary embolus was also reported. No further information about this case is available at this time.

The seriousness of the risk ranged from reports of patient death to no effects. There were 10 reports of death. One death was reported in association with recurrent PE, while the other 9 were associated with filter migration. Six (6) of these migration-associated deaths were migrations to the heart of a thrombus-encased filter. In a seventh case, only a small amount of clot was attached to the filter, but large clots were present in the pulmonary arteries. In one case, it was not known whether the filter contained clot, and in the remaining 2 cases, physicians judged the deaths to be unrelated to the filter. In the first of these 2 cases, the filter, without adherent clot, flowed out of the ventricle at autopsy. A chest X-ray taken during CPR and just prior to death did not reveal the filter in the heart, and migration to the heart may have occurred due to CPR or post mortem. In the second case, a CT scan performed minutes prior to death revealed migration to the upper IVC. In this case, an autopsy was not performed, and the physician stated that death was not related to the filter.

Likelihood of Occurrence of the Problem: The number, severity classification and type of complication (hazard) reported for the Recovery filter are summarized in Table I.

Table I. Reporting Rates for Adverse Events Associated with the Recovery Filter

Hazard type	Total	Reporting Rate	Serious Injury(as above)	Reporting Rate
Death	10(8*)	0.048%(0.038%*)	10(8*)	0.048% (0.038%*)
Migration	25	0.12%	16 (14*)	0.077% (0.067%*)
Fractures	33	0.158%	12	0.058%
Perforation	15	0.072%	1	0.005%
P. embolus	3	0.014%	3	0.014%
[IVC Thrombosis	1**	0.005%	1	0.005%]
Total	76**	0.365%	32 (30)	0.153% (0.149%)

* Number and rates if the 2 migration-associated deaths that were judged not related to the filter are excluded.
** Recurrent pulmonary embolism was also reported in this case; therefore, the total number of patients/reports is listed as 76 and not 77.

A summary of reported rates for these filter-related complications in the literature is provided in Table II..[3] These rates refer to the use of permanent, non-removable filters.

Table II. Reported Rates of IVC Filter Complications Provided by Literature Review.
Threshold levels are quality improvement guidelines published by the Society of Interventional Radiologists. Reference: Grassi CJ, Swan TL, Cardella JF et al: Quality improvement guidelines for percutaneous permanent inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol 2003;14:S271-S275.

Hazard type	Reported rates		Threshold (for review)
Death	0.12%		< 1%
Filter Embolization*	2-5%	2%	
Fractures	2-10%		Not listed
Perforation	0-41%		Not listed
P. embolus	0.5-0.6%		5%
IVC Occlusion**	2-30		10%

* This is equivalent to Migration in the Table above listing Recovery reporting rates
** This is equivalent to IVC Thrombosis in the Table above

Likelihood of Harm if the Problem Occurs: See above for the reporting rates of serious injury, defined as described in **The Actual Occurrence of Injuries**.

Is the Product Essential to Health: Yes, in selected patient groups. As mentioned above, a general consensus exists for the utility of IVC filters in high risk patient groups despite the lack of definitive RCTs.

Is there an Alternative Available: Yes. Alternative permanent and removable IVC filters exist. However, the Recovery filter is unique in the length of the implant period. The Recovery implant period is not limited in the Recovery instructions for use (IFU), and can be utilized as a permanent filter. The clinical experience for the other removable filters, as discussed in the product IFUs, reports short implant periods (mean implant period about 2-3 weeks) before filter removal must be undertaken.

Must the Problem Device be Removed or Corrected Surgically: Yes, in some cases.

Is the Problem Expected & Within an Acceptable Statistical Range: From the analysis of the MAUDE and IMS databases, Recovery reporting rates are significantly higher than those of other filters. In conjunction with these data, there appears to be a significant correlation, although R^2 values are only in the 0.5 range, of the migration reporting rates with the simulated migration resistance bench test. However, the flaws in the data collection methodologies makes calculation and comparison of actual incidence rates impossible from these data, and no definitive conclusions as to relative performance can be made. Adverse events rates reported in the literature are well above these reporting rates. But, as discussed above, direct comparisons of reporting rates to literature-derived rates are not possible because mostly permanent filters have been studied and the data have been collected using markedly different detection methods and patient populations. However, further investigation of these reported adverse events is warranted because of the size of the differences in the reporting rates and the correlation with the bench test of migration resistance.

Can the Problem be Corrected in the Field: No.

Is the Problem or Health Hazard Obvious to the User: No.

Can the Product Continue to be Used with Proper Warnings: One could consider providing summary information concerning the analysis of reporting rates to physicians in the context of the limitations of the data. Further work into the collection of survey data from surgeons or payors might be explored.

Is the Device Used Only by Specially Trained Health Care Professionals: Yes.

References:

[1]. Goldman SA. Limitations and strengths of spontaneous reports data. Clin Ther 1998; 20 Suppl C: C40-44.

[2]. Jones JK. Spontaneous reports cannot serve as a basis for comparison of two drugs. Am J Cardiol 2003;92:1141-1142.

[3]. Grassi CJ, Swan TL, Cardella JF, et al: Quality improvement guidelines for percutaneous permanent inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol 2003;14:S271-S275.

EXHIBIT 37

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

KEVIN PHILLIPS,	)	
	)	
Plaintiff,	)	Case No.
	)	3:12-cv-00344-RCJ-WGC
vs.	)	
	)	
C.R. Bard, INC., et al.,	)	
	)	
Defendants.	)	
	)	

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

PAMELA B. CASON and KERRY B. CASON,	)	
	)	
Plaintiffs,	)	
	)	Case No.
vs.	)	1:12-CV-01288-MHS
	)	
C.R. Bard, INC., and Bard PERIPHERAL VASCULAR, INC.,	)	
Defendants.	)	
	)	

30(B)(6) VIDEOTAPED DEPOSITION OF C.R. BARD, INC.
TAKEN THROUGH CHAD MODRA

Phoenix, Arizona
March 28, 2013

BY: KIM BATA, RMR/CSR
Certified Reporter 50233

Q. And then the event box it says, "RNF product is placed on QA hold pending completion of remedial action plan."

Do you see that?

A. Yes.

Q. What's a QA hold?

A. It's a control mechanism within our distribution center that when we identify something we want to investigate further, we would place a QA hold on the product pending that investigation.

Q. Okay. Does that mean it's not being sold during that time?

A. Yes.

Q. Okay.

A. Yes, it means it is not sold.

Q. During the period that a hold is placed?

A. That's correct.

Q. Okay. And is RNF Recovery? Is that a Recovery Filter?

A. That would be my assumption.

Q. And do you know why a QA hold was placed on the Recovery Filter on April 14, 2004?

send out the notification and they acknowledge it and send it back that it's been placed on hold.

Q. And is that a method by which to ensure that none of those products were actually being sold during the time that the hold is in place?

A. Yes.

Q. Okay. Are physicians in the field using the products notified that there's a hold on the product?

A. No.

Q. So although Bard's not selling it, they've placed a hold on it, physicians may still be implanting it?

A. Yes.

Q. If you could turn to Bates range ending in 2828.

A. Yes.

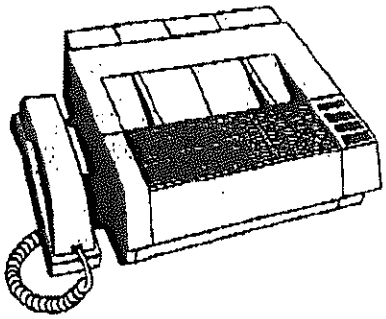
Q. The date entry is 4/25/2004, and on the event box it says, RNF product QA hold is lifted upon receipt of conclusions from HHE by Dr. Lehmann, L-e-h-m-a-n-n.

A. Yes.

EXHIBIT 38

C. R. BARD, INC.
730 CENTRAL AVENUE
MURRAY HILL, NJ 07974

Fax# 908-277-8087
Tel # 908-277-8341
E-Mail: paula.pizzi@crbard.com



FAX

TO: Mary Edwards

FROM: Paula Pizzi for Paul Kowalczyk

DATE: May 11, 2004

NUMBER OF PAGES INCLUDING COVER SHEET: 56

If transmission is not complete, please notify sender at (908) 277-8341.

COMMENTS:

Church, Nikki

From: Barry, Brian
Sent: Monday, May 10, 2004 4:05 PM
To: 'Kimberly Ocampo'; Church, Nikki
Cc: Ganser, Christopher; Kowalczyk, Paul
Subject: RE: Latest Bard Filter Plan and Q&As

Kimberly:

Hi, per my discussion with Chris Ganser, this piece will need to go through the standard Bard approval process for external pieces.

To that end, per copy of this email I am forwarding this piece to Nikki Church of our law Department, who coordinates such reviews. Nikki, please log and route per standard procedure.

Thanks

Brian

Brian R. Barry
V.P. Corporate Regulatory & Clinical Affairs
C.R. Bard Inc.
730 Central Avenue
Murray Hill NJ 07974

908-277-8062
908-277-8087 (fax)
908-472-5177 (cell)

-----Original Message-----
From: Kimberly Ocampo [mailto:kocampo@HillandKnowlton.com]
Sent: Monday, May 10, 2004 11:24 AM
To: Barry, Brian
Subject: FW: Latest Bard Filter Plan and Q&As

Hello Brian. Please see below. I'm not sure if I was given the correct spelling of your last name. Thank you.
-----Original Message-----
From: Kimberly Ocampo
Sent: Monday, May 10, 2004 11:19 AM
To: 'brian.berry@crbard.com'
Cc: Lee Lynch; 'Glass, Holly'; 'jlehmann@lehmannthomas.com'; Passero, Donna; 'Hudnall, Janet'; 'john.mcdermott@crbard.com'; 'christopher.ganser@crbard.com'; 'doug.uelmen@crbard.com'
Subject: Latest Bard Filter Plan and Q&As

Dear Brian:

On behalf of the Bard Team currently involved with development of the crisis plan and associated materials in support of the Recovery Filter, please review the attached draft communications plan, internal Q&A and external Q&A. These drafts incorporate the comments from the following: Dr. John Lehmann, Donna Passero, Janet Hudnall, John McDermott, Chris Ganser, Doug Uelmen and Holly Glass.

Could you please provide your edits and comments to Hill & Knowlton (Lee Lynch at llynch@hillandknowlton.com or 571.214.8799 or myself) by close of business, Wednesday, May 12? If you have any questions about these documents, please contact Holly Glass, Lee

or myself.

Once we incorporate your changes, we will distribute the latest drafts to the entire team and schedule a call to discuss further edits next week.

Thank you.

Regards,

Kimberly Ocampo

Kimberly Ocampo
Senior Account Supervisor
Hill & Knowlton Washington, D.C.
p: (202) 944 1905
c: (202) 997 4420
f: (202) 944 1970
kimberly.ocampo@hillandknowlton.com

HILL & KNOWLTON

"Best in International PR -
– Thomas L. Harris/Impulse Research

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HILL & KNOWLTON

MEMO

To: **Holly Glass, Chris Ganser, Janet Hudnall, Donna Passero and Brian Berry**

From: **Lee Lynch and Kimberly Ocampo**

Date: **May 10, 2004**

Subject: **Recovery Filter Crisis Communications Plan**

This document provides a step-by-step guide for implementing an immediate communications strategy to ensure C.R. Bard is prepared for any news coverage that may result from pending investigations surrounding the Recovery Vena Cava Filter.

The information presented in this plan is privileged and confidential and is for internal use only.

RECOVERY® FILTER CRISIS COMMUNICATIONS PLAN **5/10/04**

OVERVIEW

As with previous crisis plans Hill & Knowlton has prepared for C. R. Bard, this guide will help Bard's Corporate Communications Team prepare for and properly manage controversial or negative stories surrounding the Recovery® Vena Cava Filter.

The proliferation of unfavorable press in top-tier media outlets can cause an onslaught of negative activity: a company's employee morale may suffer, stock prices may plummet, analysts may downgrade the affected company's rating, and longstanding reputations may be ruined temporarily or even permanently. Extensive preparation is critical to help prevent the spread of damaging coverage.

Currently, Bard is investigating the reported migration of the Recovery Vena Cava Filter in two separate incidences.

The first reported incident under investigation took place at ~~Baptist Hospital of Miami, FL~~ following bariatric surgery. The coroner's report states that filter migration is the cause of death. Bard is conducting its own investigations to research the validity of this claim and ~~hired Dr. Luke Brennecke of Pathology Associates in Frederick, MD~~ to conduct a subsequent pathological evaluation of the thrombus surrounding the vena cava filter removed during the autopsy.

The summary ~~provided in the CMP12933 PATH Report signed by Dr. Brennecke~~ follows:

The clot formation was an ante mortem event; it had most likely been deposited around the device over a period of a couple of days. The location of the device during clot deposition could not be determined. The bacterial colonizing the clot most likely represents post mortem growth of normal saprophytic bacteria. Because extensive (destructive) sampling of the clot was prohibited (telephonic instructions), no tissue was sampled from around the hooks that were still embedded within the clot. Should they be sampled, it is possible that segments of the mural architecture (IVC or elsewhere) might be present.

It is important to note that, according to hospital records, the patient was a morbidly obese male weighing between 450 – 500 lbs. The filter was placed in a normal sized vena cava and there were no immediate complications. ~~According to a Pathology Associates report~~, the filter was found to be intact, and the large thrombus surrounding the filter was approximately 10 cm long X 3 cm in diameter. To date, no formal lawsuit from the family of the deceased has been filed.

The second incident took place in Grand Rapids, MI. From the information available to date, we know that the Recovery Filter was placed in a female patient for deep vein thrombosis. The filter had been placed approximately 13 days prior to death, March 31, 2004. The patient was then released from the hospital on April 6, 2004 and expired on April 13, 2004. The medical examiner's report states that the cause of death is cardiac rupture as a result of a puncture to the right ventricle by an inferior vena cava filter.

The size of the clot at the time of the autopsy was approximately 3 cm in diameter by 50 cm in length. There were no design or manufacturing defects found to be associated with the filter. The BPV Product Assessment Team has concluded that the Recovery Filter captured a large embolic load with resulting increase in venous pressure that lead to inferior vena cava dilation greater than 28 mm resulting in migration. Final autopsy report will be available during the week of May 4.

The attached pages provide recommendations and critical information relating to the following components of your crisis communications program:

- I. Re-distributing Bard's Communications Policy
- II. Media Monitoring
- III. Message Approval
- IV. Establishing A Core Response Team
- V. Audience Outreach Team
- VI. Top Media Interview Dos and Don'ts
- VII. External Allies/Experts
- VIII. Key Studies
- IX. News Breakdown
- X. Newsmaker's Bill of Rights
- XI. Proactive Media Outreach
- XII. Step-by Step Management of Most Likely Scenarios:
- XIII. H&K Team Contact Information
- Addendum:
  - A. Key Messages – Recovery Vena Cava Filter: General Messages
  - B. Key Messages for Specific Incidents:
    - Specific to Miami Incident
    - Specific to Grand Rapids, MI Incident
    - Specific to Both Incidents
  - C. Draft General Letter-To-The-Editor
  - D. Draft Miami Letter-To-The-Editor
  - E. Draft Miami Letter-To-The-Editor
  - F. Media Lists
  - G. Recent Sample Article: Bariatric Surgery in General

I. Re-distributing Bard's Communications Policy

To prevent any Bard employee from speaking with members of the media, it would be wise to redistribute Bard's communications policy company-wide twice each year beginning with 2Q 2004. If Bard is notified that a lawsuit has been filed, dissemination of the communications policy *again* specifically to the Bard Peripheral Vascular Division as well as C.R. Bard Corporate employees, should be considered.

Anyone who may be most likely to receive phone calls from members of the media (e.g., administrative staff for corporate executives and field sales representatives who sell vena cava filters) must have copies of the communications policy and should be required to sign a confirmation form that they have read and understand these guidelines.

All Bard employees must know to direct any media inquiries directly to Holly Glass. With the communications guidelines redistributed several times each year, employees will have this information top-of-mind.

II. Media Monitoring

H&K has begun monitoring regularly for any print, broadcast and online news coverage related to the company or the Recovery Vena Cava Filter. To do this effectively, H&K is using the Factiva database, Google News and Video Monitoring Services (VMS). Particular emphasis is placed on news generated from the following markets: greater New York City (Bard Corporate HQ); Tempe, Arizona (Bard Peripheral Vascular HQ); Miami, Florida (location of case under investigation) and Grand Rapids, Michigan (location of case under investigation).

We are searching for the following terms.

- C.R. Bard
- Bard Peripheral Vascular
- Recovery Vena Cava Filter
- Vena cava filter
- Pulmonary embolism
- Baptist Hospital (Miami, FL)
- Miami Cardiac & Vascular Institute (MCVI)[NA1]
- [NAME OF LAW FIRM FILING SUIT IF SUIT IS FILED]
- Any filter mentions in Grand Rapids, MI

III. Message Approval

Key messages (see appendix; still to be reviewed and finalized) serve as the foundation for responding during any media interviews that may arise as a result of the pending investigations. It is critical that this messaging be updated as new details arise.

The approved messaging will be incorporated into external materials that will be distributed to Bard's sales force, customers, physicians, employees, suppliers and others, as needed. Bard is then prepared to handle any media inquiries. Furthermore, H&K's on-camera Q&A Training will help prepare spokespeople for any local or trade press inquiries that are posed; additional "on-the-spot" training and messaging discussions should be considered prior to responding to national top-tier press inquiries.

IV. Establishing A Recovery Core Vena Cava Filter Response Team

The following Bard and H&K employees should comprise the Core Response Team (CRT) for the Recovery Vena Cava Filter product. These individuals will receive notification when a press inquiry is received or when a negative article requiring action appears. This group will convene within several hours to approve response strategy, review specific messaging and determine next steps.

Core Response Team:	Phone Numbers:	E-mail Address:
Holly Glass	Office-703-754-2848 Cell-571-243-1952 Home-571-261-1425	holly.glass@crbard.com
Janet Hudnall	Office-480-303-2630 Cell-602-881-1331	janet.hudnall@crbard.com
Donna Passero	Office-908-277-8335 Cell-908-803-9346 Home-973-394-0052	donna.passero@crbard.com
Chris Ganser	Office-908-277-9338 Cell-908-568-9411 Fax-908-277-8087	christopher.ganser@crbard.com
Doug Uelmen	Office-480-303-2629 Cell-TBD Home-TBD	doug.uelmen@crbard.com
John McDermott	Office: 480-303-2673 Cell: 602-684-7309	john.mcdermott@crbard.com
Rob Carr	Office: 480-303-2684 Cell: 480-220-2322	robert.carr@crbard.com
Brian Berry	Office: Cell:	brian.berry@crbard.com
Adjunct – John Lehmann, MD	Office-617-489-7080 Cell-508-341-8942 Home-508-358-5365	jlehmann@lehmannthomas.com
Frank Mankewicz	Office-202-944-5141 Cell-202-258-9020 Home-202-462-7202	fmankiewicz@hillandknowlton.com
Lee Lynch	Office-202-944-5186 Cell-571-214-8799	llynch@hillandknowlton.com
Kimberly Ocampo	Office-202-944-1905 Cell-202-997-4420	kocampo@hillandknowlton.com

CRT Conference Calls
The following telephone line is available 24 hours a day, seven days a week for the CRT to use for conference calls.

- Toll Free Dial-In Number: 1-888-453-5732
- Participant Passcode: 500965

V. Recovery Vena Cava Filter Audience Outreach Team

Depending on the situation, the CRT may determine that there is a critical need to contact other key audiences outside of this immediate response group. To facilitate effective and efficient communications among the various company divisions and appropriate external audiences, a point-of-contact has been designated to conduct this outreach. They are:

Audience Outreach Team:	**Phone Numbers:**	**E-mail Address:**
Additional Media: Holly Glass	Office-703-754-2848 Cell-571-243-1952 Home-571-261-1425	holly.glass@crbard.com
CEO and Board of Directors: Holly Glass	Office-703-754-2848 Cell-571-243-1952 Home-571-261-1425	holly.glass@crbard.com
Recovery Filter Field Sales Reps: Janet Hudnall Carol Stone	Janet: Office-480-303-2630 Cell-602-881-1331 Carol: Office-908-277-8301 Cell-908-507-6574 Home-908-526-5579	janet.hudnall@crbard.com carol.stone@crbard.com
Recovery Filter Physicians: Janet Hudnall	Office-480-303-2630 Cell-602-881-1331	janet.hudnall@crbard.com
Customers and Field Reps: Janet Hudnall	Office-480-303-2630 Cell-602-881-1331	janet.hudnall@crbard.com
All Other Employees: Diana McHugh	Office-908-277-8191 Cell-908-571-2841 Home-908-835-0107	diana.mchugh@crbard.com
Suppliers/Operations: Frank Maloit	Office-908-277-8177 Cell-908-528-3537 Home-610-330-9082 Home-781-837-9530	frank.maloit@crbard.com
Shareholders and Wall Street: Eric Shick	Office-908-277-8413 Cell-908-256-4238 Office- 908-277-8265	eric.shick@crbard.com

VI. Top Media Interview Dos and Don'ts

Following is a list of general dos and don'ts for interviews with major top media outlets.

Dos

- Offer a physician spokesperson for comment.
- Offer a researcher, patient or corporate executive for further insight.
- Offer medical studies validating Recovery Vena Cava Filters or retrievable vena cava filters in general.
- Ask for a list of questions, parameters of the story and permission to record your own video of the interview or any interviews with Bard employees, patients or physicians.
- Offer video of Bard's headquarters, if you already have a tape available.
- Manage the story. Draw the line at non-company spokespersons, "trial witnesses", salespersons, product designers, etc.
- Stay focused on the success rate and clinical effectiveness of the products, rather than the claims. Stick to your key messages.
- Include day-before and day-of key audience notification in your communications strategy. Assume key audiences such as employees, physicians, shareholders, customers and field sales reps will see the story. Be prepared to notify them about when the segment will air or has just aired, and provide a clear, convincing cover letter with your key messages, as well as a breakdown of comments made in the story matched with corresponding facts.

Don'ts

- Play favorites with the members of the media.
- Answer a question with "No Comment."
- Don't try to minimize the problem.
- Don't release sensitive or proprietary information.

VII. External Allies/Experts

Physician Spokespeople
If a reporter calls for comment, Bard should have reputable physicians confirmed to participate in interviews to attest to the product's success rate and the value it provides to patients.

The below physician has been identified to serve as a spokesperson who can speak to the value of the filter.

Gary S. Cohen, MD
Chief, Interventional Radiology
Temple University Medical Center
3401 N. Broad St.
Philadelphia, PA 19140
(215) 707-3951
cohenator@aol.com

Third Party Industry Organizations and Potential Allies
Board members and other prominent leaders from ally organizations may be able to lend their credibility to Bard by providing ally spokespersons who can speak to the value of the retrievable Recovery Vena Cava Filter products (or retrievable vena cava filters in general) and Bard's position as a leader both in terms of innovation and customer care/safety. Allies may include representatives from the following organizations:

- Society of Interventional Radiology
- Association for the Advancement of Medical Instrumentation
- Medical Device Manufacturers Association
- Society for Vascular Surgeons

We currently are researching whether these organizations would be willing to speak to the media if an inquiry arises. For regional or local media outlets, it may be necessary to provide local sources. As the scenario develops, we may work with other third-party associations to determine local spokespeople.

In addition, Bard may want to consider either securing the partnership of a general medical device or consumer organization that can speak broadly about the value of Bard's products for consumers, such as:

- The Medical Device Manufacturers Association
- Center for Consumer Affairs or
- American Council on Consumer Interests (ACCI)

Finally, another consideration is for Bard to create a third-party organization that focuses on the enormous benefit of medical progress for consumers to override the negative perceptions created through a few (often frivolous) lawsuits.

VIII. Key Studies

Two studies are available specific to the Recovery Filter.

The Recovery Filter has been used in Canada by a single investigator and two colleagues at six Toronto area hospitals in 58 subjects, under the Special Access regulations. Although essentially only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment.

Of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 [NA2]patients have died with filters in place of causes unrelated to filter placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, average 60 days.

In addition, the Recovery Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

[NEED ABSTRACTS FOR THE ABOVE AND ADDITIONAL HUMAN STUDIES]

Summaries of key medical studies highlighting the success rate of Bard's Recovery Vena Cava Filter products and other vena cava filters can be found in the appendix. We have produced three separate sections of summarized studies: one focuses on the success of (permanent) [NA3]vena cava filters in general; the second focuses on retrievable vena cava filters as a whole; and the third details studies on Bard's Recovery Vena Cava Filter specifically. These summaries will serve as handouts and references for the media.

IX. News Breakdown

There are many various forms a news story can take and often one precedes another. To understand how news stories are originally generated and often end up featured on weekly news magazine shows, an explanation of how the media generally works is provided below. Please note there are always exceptions to the standards.

Wires – Associated Press, Bloomberg, Dow Jones, Reuters
National Dailies – *USA Today, New York Times, Wall Street Journal*
Top Market Dailies – *Los Angeles Times, Boston Globe, Washington Post*
Trades – *The Gray Sheet, MDDI, Medical Device Litigation Reporter*
News Magazine – *U.S. News & World Report, Time, Newsweek*
Daily News Program – Dateline, World News Tonight
Weekly News Program – 60 Minutes, 60 Minutes II, 48 Hours Investigates, 20/20

Wires
Electronic wire services are the most immediate sources for breaking news. Wire stories have the most power in terms of garnering national attention and generating widespread coverage because they are "picked up" by all media outlets. Since these stories are published in real time, they are often very short and have limited third-party sources. Many times, these stories are updated continuously as the story develops throughout the day or week.

National and Top Market Dailies
Most newspapers subscribe to wire services and look to the wires to determine news assignments. While many leading papers run complete wire stories, often editors use a wire story as a starting point to develop the story with local tie-ins, such as the story's impact on the community or using local experts for attributions. As a side note, nearly all newspapers will immediately post full wire stories on their Web sites.

Trade Publications
The trade journals are very influential in the medical device industry and will certainly be read by Bard's competitors. They will cover the issue in-depth and may discuss its impact on the entire industry. Trade coverage may also lead to more general coverage.

News Magazines
News magazines will typically develop a story based on an initial wire story, and/or news item in a top daily or trade publication. However, these publications will provide a much more in-depth analysis of the issue. They will conduct extensive research on the companies involved and the sources being used in the story. They dig deep and uncover information that is often under the radar. These stories can take weeks to develop.

Broadcast
As a general rule, broadcast follows print. Once the print story hits, broadcast interest in the story will likely escalate.

For daily broadcast segments, producers will either request an interview with a Bard spokesperson to take place at the local affiliate station or arrange for a video crew to come to Bard's headquarters. Broadcast segments on nightly news programs can take several days to develop.

Weekly programs like "60 Minutes" or "48 Hours" can take several weeks or even months to develop. Producers also will send a crew to the corporate headquarters to film the facility and interviews. They will likely make numerous trips to Bard's headquarters. They will conduct extensive interviews and ask pointed questions.

X. Newsmaker's Bill of Rights

As we respond to media inquiries and arrange interviews, remember that Bard has certain rights as newsmaker and reporters have their expectations.

1. The right to know the interview topic(s) in advance.
2. The right to know the identity and affiliation of the reporter.
3. The right to state your key points and, if appropriate, restate them.
4. The right to have some control over the interview environment.
5. The right to bring up relevant topics and points not specifically asked during questioning.
6. The right to know how the interview material is being used and whether others are being interviewed for the story.
7. The right to respond to accusations.
8. The right to correct misstatements and misinformation during an interview.
9. The right to restate obscure or lengthy questions.
10. The right to finish responses without interruption as long as your answer is concise and relevant.

Reporter's Expectations

1. Reasonable access to legitimate news sources.
2. Consideration of the reporter's deadline and logistical needs.
3. A timely response to an inquiry.
4. A concise and direct answer to a relevant question.
5. If available, printed or pictorial material to flesh out the interview information.
6. The availability of corporate spokespersons for follow-up inquiries, when necessary, for clarification.
7. Corrected information, if incorrect information is inadvertently given.
8. Proactive follow-up by newsmaker with new information or corrected information.
9. An opportunity to build an ongoing relationship.
10. The same kind of courtesy and respect that the newsmaker desires.

XI. Proactive Media Outreach

We do not recommend proactive outreach to media at this time. We believe that taking a low-key approach, in an effort to avoid drawing attention to the issue, is the most appropriate strategy.

XII. Step-by Step Management of Most Likely Scenarios

Note: If any of these scenarios occurs, H&K will immediately implement the Bard News Bureau, through which H&K's Bard Team members (Frank Mankiewicz, Lee Lynch, Kimberly Ocampo and Melissa Busse) will work with other members of H&K's Media/Crisis/Litigation team and CR Bard Vena Cava Core Team members to determine and implement strategy and media outreach.

Scenario #1: Family of the deceased files a suit seeking damages from C. R. Bard. [LAW FIRM] issues a press release.

1. H&K will monitor any press announcements made by the plaintiff's law firm, as once a press release is issued, it may generate news coverage.
2. If a press release runs on the wire, H&K will send an email to the Core Response Team. The email will include the press release and any other relevant information. H&K will also call Holly Glass, Janet Hudnall and Donna Passero with this information.
3. H&K will immediately begin to monitor for any resulting press coverage.
4. As soon as press coverage begins to appear, we will activate the CRT:
    a. H&K will send e-mails to the CRT, including press coverage to date if available and a scheduled conference call time.
    b. H&K will follow up with phone calls to all CRT members, informing each member of the upcoming conference call.
    c. During the call, CRT members will agree on media strategy and responses. Strategy may include contacting reporters responsible for coverage and providing them with summarized studies and a statement based on approved key messages from the company.
    d. As determined, CRT members may be responsible for informing Audience Outreach Team members.
5. H&K will continue to monitor for additional coverage.

Scenario #2: A reporter calls Bard for comment.

1. The media inquiry comes in to Holly Glass.
2. Holly will notify Lee Lynch at H&K.
3. Depending upon the size and reach of the news outlet, either H&K or Holly Glass will call the reporter to find more information about the type of questions he or she may ask.
4. H&K will provide, through e-mail to the CRT, the list of anticipated questions and a time for a strategy conference. H&K also will gather and distribute to the team as much information as possible about the reporter.
5. H&K will follow up with phone calls to all CRT members, informing each member of the conference call.
6. During the call, the CRT members will agree on media responses.
7. As determined, CRT members may be responsible for contacting Audience Outreach Team members to inform them of the interview and pending coverage.
8. Holly Glass will conduct the media interview with H&K facilitating as appropriate. Summarized studies will be provided to the reporter.
9. H&K will follow up with the reporter as necessary.
10. H&K will put together a document detailing potential impact of the pending article (e.g., tone of interview, reach of wire service if interview was conducted by wire reporter, etc.) and recommended next steps.
11. H&K will monitor for resulting and additional coverage.

Scenario #3: Filter migration or bariatric surgery (see example of recent negative story in appendix), in general, gets negative media coverage without singling out Bard or the Recovery Filter.

1. H&K will research the background of the reporters writing the negative stories and will forward this information, along with copies of the articles, to Holly Glass.
2. Holly Glass and H&K will determine the appropriate response (if any) on a case-by-case basis. Response may include the development of a letter-to-the-editor, pitching a "reactive" or follow-up interview to reporters in an effort to preempt any negative stories being written about Bard and its filter product and/or to help position Bard as a leader in this category.
3. If the scenario requires the development of a letter-to-the-editor, H&K will tailor the attached template, as required, and will forward the draft to all CRT members for review and approval.
    a. H&K will contact all CRT members to set up a time for a conference call.
    b. During the conference call, the CRT will review, edit and approve the letter.
    c. If the letter will be signed by a physician, H&K and Holly Glass will work to secure the physician spokesperson's approval and forward an edited version to the CRT for final review.
    d. H&K will forward the letter to the appropriate editorial contacts and monitor for coverage.
4. If the scenario requires an interview, H&K will provide Holly Glass with quick "refresher" course on media coaching tips and techniques.
    a. Holly Glass, H&K and the Audience Outreach Team will determine the appropriate messages and communications vehicle to inform Bard's key constituents prior to the airing of the program.
    b. Holly Glass will conduct the media interview with H&K facilitating as appropriate. Summarized studies will be provided to the reporter.
    c. H&K will follow up with the reporter as necessary. H&K may arrange a follow-up interview with the physician spokesperson and/or a patient, as determined if necessary.
    d. H&K will put together a document detailing potential impact of the pending article (e.g., tone of interview, reach of wire service if interview was conducted by wire reporter, etc.) and recommended next steps.
    e. H&K will monitor for resulting and additional coverage.

Scenario #4 – News Bureau – A major news story breaks about the lawsuit and the "snow ball" effect kicks in, generating much negative media coverage on Bard and the Recovery Vena Cava Filter.

If this scenario occurs, H&K will immediately implement its Bard News Bureau to respond to all incoming media inquiries efficiently and effectively.

Media Contact Lists

H&K has identified the most likely reporters to write stories on lawsuits, based on past research for the mesh hernia repair product crisis plan. We have also identified the following:

- Legal and healthcare beat reporters at the wire services, top 25 daily newspapers and top financial news outlets
- Editors at health and medical device trade publications
- Editorial board contacts at the top 25 dailies, should Bard want to proactively secure background meetings with these influential reporters
- News directors at the major networks broadcast affiliates (NBC, ABC, CBS, and Fox) in Bard's key markets relating to the investigation (presently, Miami, FL and Grand Rapids, MI)

Following this document are the identified media outlets.

Toll-Free Line for Reporters

When and if necessary, Bard may consider activating a toll-free number, manned by appointed, trained persons to take messages of all incoming media inquiries. H&K can implement this phone line within hours.

Call Reports

As media inquiries come in, H&K will format all information regarding incoming media calls into call reports and submit these reports to Holly Glass. These reports will include the date and time of the initial inquiry, the name of the reporter, his/her publication, beat, purpose of call, questions he/she may have and dates and times of interview request. H&K will also gather as much information about each reporter as is available.

Prepared Statements

Depending on the amount of media inquiries and the rate at which they come in, it may be necessary to distribute a previously prepared statement. A sample statement has been created and approved by legal counsel. This statement reflects Bard's inability to comment on pending litigation and reinforces the need for approved key messages. It can be easily modified to address specific inquiries from media or new developments in pending cases.

If it is necessary, Bard may issue the prepared statement on PR Newswire. H&K has an existing account with PR Newswire already established.

The statement may be updated as Bard develops its position or as new information is gathered and actions are taken.

News Monitoring

H&K will continue to conduct daily monitoring for any stories related to litigation. For wire and print stories, H&K uses the Factiva Database, for online stories, H&K searches Google and Google News, and for broadcast stories, H&K works with VMS. VMS is monitoring nationally, but placing extra emphasis on markets where incidents are under investigation. H&K will prepare a report assessing the news coverage on a daily basis during the crisis situation, or as necessary.

News Evaluation

After the media coverage is generated and interest has dwindled, H&K will critique the coverage and provide an overall analysis of the scenario and make specific recommendations.

News Conference

In most situations, news conferences are neither necessary nor desirable. However, Bard should be prepared to move forward quickly with a news conference if deemed necessary. Holding a news conference should be considered when:

- ⇒ Written or electronic dissemination of a statement will not satisfy the media covering the situation.
- ⇒ The situation is extremely serious and media requests have reached a level or volume when they no longer can be handled through individual telephone calls.
- ⇒ Company actions can be best explained through a news conference that reaches all media at the same time with information, personal statements and visual documentation.

The major disadvantage to holding a news conference is that the forum allows for rigorous and potentially damaging questioning. News conferences can require intense preparation for the spokesperson and the CRT, including further message development, question anticipation and spokesperson training.

H&K will coordinate all logistics, including announcement, location, time, audio/visual equipment.

1. Announcement: H&K will draft the news conference announcement and distribute it across PR Newswire. The announcement will mention the issue, and list the spokesperson, time, location and contact for further information. Pending on the scope of the situation, this information may also be posted on Bard's Web site. Following the distribution of the announcement, H&K will follow up with telephone calls to obtain a preliminary headcount and identify key reporters.

2. Location: The location will be convenient for reporters and Bard executives. There will be a separate entrance and exit for the spokesperson, so he/she is not forced to wind through rows of reporters to get to the podium or to exit the facility.

3. Audio Visual Equipment: H&K will coordinate the rental or usage of all a/v equipment, including a podium, microphones, video camera, etc. Bard should tape the conference for its own records.

4. Materials: Bard press kits will be made available to all attendees, containing all collateral materials including fact sheets, recent press releases and executive biographies.

5. Agenda: H&K will develop a specific agenda for the news conference. The spokesperson will note the agenda and the specified timeline of the event.

6. Outside speakers: As the situation is evaluated, H&K may advise having a physician or third-party organization (industry) spokesperson available to answer specific medical-related questions.

Scenario #5 – News Bureau – Another negative migration case causes Bard to remove the Recovery Filter from the market.

1. Janet Hudnall contacts Holly Glass, who notifies H&K.
2. H&K immediately begins to monitor for news, coordinate a CRT conference call and prepare for roll out of News Bureau activities.
3. During the call, Donna Passero talks the CRT through the product recall process. The CRT determines the appropriate strategy, messaging and next steps.
4. Following the call, H&K provides the action items resulting from the call and an outline of CRT members' roles and responsibilities.
5. In conjunction with Holly Glass, H&K will draft all tactical plans and response materials, including initial statement customized according to audience (e.g., media, Wall Street, Bard employees, sales force, customers and physicians).
6. H&K coordinates follow-up call with both CRT and Audience Outreach Team to review materials and secure approval.
7. Audience Outreach Team notifies its appropriate target audiences.
8. H&K and Holly Glass activate the News Bureau, as outlined above in Scenario #3.

Scenario #6 – A competitor tips off media.

Any of the above scenarios may play out.

XIII. H&K Team Contact Information

Frank Mankiewicz – Senior Counselor
Office: 202-944-5104
Cell: 202-258-9020
Home: 202-462-7202
Assistant: Laurel Laidlaw – 202-944-5141

Lee Lynch – Account Management
Office: 202-944-5186
Cell: 571-214-8799
Home: 703-823-3926

Kimberly Ocampo – Media Specialist and Key Support
Office-202-944-5193
Cell-917-584-7961
Home-202-248-2337

Melissa Busse – Key support
Office-202-944-3365
Cell-703-786-9423
Home-703-465-9619

Appendix

A. Key Messages – Recovery Vena Cava Filter: General Messages

1. The Recovery Vena Cava Filter, a Bard Peripheral Vascular product, is a well designed and tested inferior vena cava (IVC) filter that, when properly placed and intact, helps to reduce or prevent the risk of blood clots traveling to the lungs or heart.
   - [NA4]The Recovery Vena Cava Filter is indicated for use as both a permanent and retrievable device to reduce and prevent any blood clots from the legs that may break off and travel, or "migrate", through the bloodstream to the lungs or heart.

2. The Recovery Vena Cava Filter is proven in its safety and efficacy.
   - A properly placed filter can resist the force of a fair amount of blood clot; however, large clots and the forces of exertions, such as bowel movements, can overwhelm *any* filter's retentive capability, resulting in possible migration. *This is true for all IVC filters.*
   - Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

3. The retrievability of the device is valuable and appealing from a clinical perspective to medical professionals and patients.
   - Retrievable filters are designed to be removed once the risk of pulmonary embolism has subsided.
   - The actual filter mechanism works exactly the same in retrievable and non-retrievable filters. Non-retrievable filters cannot be easily removed without injury to the patient.

4. At Bard, our number one priority is our commitment to our patients.
   - With any report of an adverse event, we take an immediate, systematic approach and form a multi-disciplinary team to thoroughly investigate the incident.
   - Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take our responsibility to patients very seriously.
   - Bard has been in business for nearly a century, and we are known for our commitment to providing innovative, life-enhancing medical technologies.

B. Key Messages:

Specific to Miami Incident:

1. We have been notified of the death of a patient whose medical treatment in Miami included the insertion of Bard's Recovery Vena Cava Filter. First and foremost, we extend our deepest sympathies to the patient's family. At Bard, our number one priority is our commitment to our patients.
    - Bard has been in business for nearly a century, and we are known for our commitment to providing innovative, life-enhancing medical technologies.

2. With any report of an adverse event, we take an immediate, systematic approach and thoroughly investigate the incident.
    - Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility to patients.

3. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event. We do know that:
    - The filter was placed in a normal sized vena cava and there were no immediate complications following surgery.
    - [NA6]The filter was found to be intact, deposited in the patient's right atrium post-mortem, and a large blood clot surrounding the filter was approximately 10 cm long X 3 cm in diameter.
    - [If asked about the relative health of the patient, please respond, "The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.].

If asked about the Grand Rapids, MI incident in the course of these messages, use the following statement: We have been notified of an incident that recently occurred in Grand Rapids, MI, involving the death of a patient whose medical treatment included the insertion of Bard's Recovery Vena Cava Filter. We have very few details that can be discussed at this point. We placed the Recovery filter on sales hold while conducting initial evaluations of the circumstances surrounding this incident. The product has since been released from hold. [NA7] [NEED TO INCLUDE CONCLUSIONS FROM THE EVALUATIONS HERE]

Specific to the Grand Rapids, MI Incident:

1. We have been notified of the death of a patient whose medical treatment in Grand Rapids, MI included the insertion of Bard's Recovery Vena Cava Filter. First and foremost, we extend our deepest sympathies to the patient's family. At Bard, our number one priority is our commitment to our patients.
   - Bard has been in business for nearly a century, and we are known for our commitment to provide innovative, life-enhancing medical technologies.

2. With any report of an adverse event, we take an immediate, systematic approach and thoroughly investigate the incident.
   - Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility to patients.

3. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event. We do know that:
   - The filter was placed in a normal sized vena cava and there were no immediate complications following surgery.
   - The Recovery filter was on sales hold while we conducted initial evaluations of the circumstances surrounding this incident. The product has since been released from hold. [NAB] [redacted]

If asked about the Miami incident in the course of these messages, use the following statement: We have been notified of the death of a patient whose medical treatment in Miami included the insertion of Bard's Recovery Vena Cava Filter. A multi-disciplinary team is thoroughly investigating the incident. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event. We do know that:

- The filter was placed in a normal sized vena cava and there were no immediate complications following surgery.
- [NAB]The filter was found to be intact, deposited in the patient's right atrium post-mortem, and a large blood clot surrounding the filter was approximately 10 cm long X 3 cm in diameter.
- [If asked about the relative health of the patient, please respond, "The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.].

If Asked About Both Incidents:

1. We have been notified of two recent, unrelated incidences. One occurred in Miami, the other in Grand Rapids, MI. We have very few details that can be discussed at this point about the Grand Rapids incident. The Miami incident involved the death of a patient whose medical treatment included the insertion of Bard's Recovery Vena Cava Filter. First and foremost, we extend our deepest sympathies to the patient's family. At Bard, our number one priority is our commitment to patients.
   - Bard has been in business for nearly a century, and we are known for our commitment to providing innovative, life-enhancing medical technologies.

2. With any report of an adverse event, we take an immediate, systematic approach and thoroughly investigate the incident.
   - Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility to patients.

3. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event. We do know that:
   - The filter was placed in a normal sized vena cava and there were no immediate complications following surgery.
   - [NA10]The filter was found to be intact, deposited in the patient's right atrium post-mortem, and a large blood clot surrounding the filter was approximately 10 cm long X 3 cm in diameter.
   - [If asked about the relative health of the patient, please respond, "The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.].

If asked specifically for more information about the Grand Rapids, MI incident, use the following statement: We have been notified of an incident that recently occurred in Grand Rapids, MI, involving the death of a patient whose medical treatment included the insertion of Bard's Recovery Vena Cava Filter. We have very few details that can be discussed at this point. We placed the product on sales hold while we conducted initial evaluations of the circumstances surrounding this incident. The product has since been released from hold. [NA11]

[NEED TO INCLUDE CONCLUSIONS FROM THE EVALUATIONS HERE]

C. Draft General Letter-To-The-Editor

MONTH XX, 2004

Dear Editor,

As a physician who has implanted more than [NUMBER] Recovery Filters, I can certainly attest to the quality of Bard Peripheral Vascular's vena cava filter product. In actual practice and in reported studies, this life-saving clot-trapping device has been proven to be safe and effective when a patient's condition indicates a vena caval filter: thrombo-embolic disease (TED) with contraindication for anticoagulation, failure of anticoagulation, massive pulmonary embolism, or chronic, recurrent pulmonary embolism.

The Recovery Vena Cava Filter plays an important role in helping to reduce or prevent blood clots from traveling to the lungs or heart. These blood clots, unimpeded, can cause pulmonary embolism that can sometimes be fatal.

As a physician[NA13], and a trainer of other physicians who implant and retrieve Recovery Filters, I come in contact with many patients and physicians who have experienced the life-protecting benefits of Bard's vena cava filter product. I can only speak for myself when I say that the retrievable nature of the Recovery Filter is valuable and an added benefit. In my experience, I have been able to safely remove the device once the risk of pulmonary embolism has been reduced.

Sincerely,

Physician's Name
Medical Facility
City

D. Draft Miami Letter-To-The-Editor

MONTH XX, 2004

Dear Editor,

(Insert name)'s article, "Insert Title" did not shed light on the proven safety and efficacy of the Recovery Vena Cava Filter. As a physician who implants more than [NUMBER] Recovery Filters a week, I can certainly attest to the quality of Bard Peripheral Vascular's vena cava filter product.

The Recovery Vena Cava Filter plays an important role in helping to reduce or prevent blood clots from traveling to the lungs or heart. These blood clots, unimpeded, can cause pulmonary embolism that can sometimes be fatal.

I can only speak for myself when I say that the retrievable nature of the Recovery Filter is valuable and an added benefit. It allows the physician to safely remove the device once the risk of pulmonary embolism has been reduced.

As a physician[NA15], and a trainer of other physicians who implant and retrieve Recovery Filters, I come in contact with many patients and physicians who have experienced the life-protecting benefits of Bard's vena cava filter product. Based on an understanding of all details surrounding the incident reported in the aforementioned article, I have to question the validity of the claims mentioned in this newspaper. These claims fly in the face of published and practice evidence supporting the safety and efficacy of Bard's innovative and effective vena cava filter product.

Sincerely,

Physician's Name
Medical Facility
City

E. Draft Grand Rapids Letter-To-The-Editor

MONTH XX, 2004

Dear Editor,

(Insert name)'s article, "Insert Title" did not shed light on the proven safety and efficacy of the Recovery Vena Cava Filter. As a physician who implants more than [NUMBER] Recovery Filters a week, I can certainly attest to the quality of Bard Peripheral Vascular's vena cava filter product.

The Recovery Vena Cava Filter plays an important role in helping to reduce or prevent blood clots from traveling to the lungs or heart. These blood clots, unimpeded, can cause pulmonary embolism that can sometimes be fatal..

I can only speak for myself when I say that the retrievable nature of the Recovery Filter is valuable and an added benefit. It allows the physician to safely remove the device once the risk of embolism has been reduced.

As a physician, and a trainer of other physicians who implant and retrieve Recovery Filters,, I come in contact with many patients and physicians who have experienced the life-protecting benefits of Bard's vena cava filter product. Based on an understanding of all details surrounding the incident reported in the aforementioned article, I have to question the validity of the claims mentioned in this newspaper. These claims fly in the face of published and practice evidence supporting the safety and efficacy of Bard's innovative and effective vena cava filter product.

Sincerely,

Physician's Name
Medical Facility
City

F. Media Lists

H&K has identified medical/health and legal/litigation reporters and editorial board contacts at the following outlets:

Wires

- Associated Press
- Bloomberg
- Copley
- Cox
- Dow Jones
- Gannett
- Knight Ridder
- McClathchy
- Newhouse
- Reuters
- Scripps Howard
- Times
- Tribune
- UPI
- Universal Press Syndicate

Top Dailies

- *The Wall Street Journal*
- *USA Today*
- *The New York Times*
- *Los Angeles Times*
- *The Washington Post*
- *Daily News* (New York)
- *Chicago Tribune*
- *Newsday*
- *New York Post*
- *Houston Chronicle*
- *Chicago Sun-Times*
- *Chicago Tribune*
- *San Francisco Chronicle*
- *The Boston Globe*
- *The Boston Herald*
- *The Dallas Morning News*
- *Miami Herald*
- *The Arizona Republic*
- *The Atlanta Constitution*
- *The Philadelphia Inquirer*
- *The Star-Ledger* (Newark)

- *Star-Tribune* (Minneapolis)
- *Detroit Free Press*
- *The Plain Dealer*
- *Rocky Mountain News*
- *Denver Post*
- *Austin Statesman*
- *Austin Business Journal*
- *[PLACEHOLDER FOR MAJOR PRINT OUTLETS IN AND NEAR GRAND RAPIDS, MI]*

Medical/Health and Legal/Litigation Reporters at Top Financial Outlets

- Bloomberg (print and broadcast)
- *BusinessWeek* and Businessweek.com
- CNBC
- CNNfn
- Dow Jones
- *Financial Times*
- *Forbes*
- *Fortune*
- *Investor's Business Daily*
- *SmartMoney*
- The Street.Com

Editors at Relevant Medical, Health and Medical Device Publications

- *The BBI Newsletter*
- *Biomedical Instrumentation & Technology*
- *Biomedical Safety & Standards*
- *BNA'S Health Law Reporter*
- *Clinica World Device and Diagnostic News*
- *Diagnostic Insight*
- *The Gray Sheet*
- *Health News Daily*
- *In Vivo*
- *The Healthcare News*
- *Medical Device and Diagnostics Industry*
- *Medical Device Daily*
- *Medical Devices and Surgical Technology Week*
- *Medical Product Manufacturing News*
- *Medical Device Litigation Reporter*

News directors at the major networks broadcast affiliates in Bard's key markets

New York/New Jersey

- WABC-TV (ABC)
- WCBS-TV (CBS)
- WNBC-TV (NBC)
- WNYW-TV (FOX)

Miami

- WPLG-TV (ABC)
- WFOR-TV (CBS)
- WTVJ-TV (NBC)
- WSVN-TV (FOX)

Phoenix/Tempe

- KNXV-TV (ABC)
- KPHO-TV (CBS)
- KPNX-TV (NBC)
- KSAZ-TV (FOX)

[PLACEHOLDER FOR MAJOR BROADCAST OUTLETS IN AND NEAR GRAND RAPIDS, MI]

G. Recent Sample Article: Bariatric Surgery in General

04/11/2004 04:19:17
As Obesity Surgeries Soar, So Do Safety, Cost Concerns
Rob Stein, Washington Post Staff Writer

Source: *The Washington Post*
Date: April 11, 2004
Section: A Section
Page: A01

The number of overweight Americans resorting to stomach-shrinking surgery is rising so rapidly that health experts and insurance companies are increasingly becoming alarmed about the safety, effectiveness and mounting costs of the operations.

While the operations can produce dramatic benefits for very obese people, some hospitals and surgeons may be rushing too quickly to satisfy the surging demand, offering the lucrative procedures without adequate training, experience and support, experts say.

At the same time, the operations, which force people to eat less by reducing the size of their stomachs, are being performed too commonly on people who might be able to lose weight through diet and exercise, particularly younger adults and teenagers, they say.

Alarm has intensified because of scattered reports of severe complications and deaths around the country. In Massachusetts, for example, a special panel has begun assessing the procedure for state health authorities after several patients died following surgeries.

Citing uncertainty about the safety of the procedures and lingering questions about their long-term effectiveness, a growing number of insurance companies have begun balking at paying for the operations, which cost the nation close to $3 billion a year.

To try to resolve some of these issues, the National Institutes of Health has launched a five-year, $15 million research project to gather data about the operations, identify patients most likely to benefit and learn more about how they work.

In the meantime, the American Society for Bariatric Surgery, which represents surgeons who perform the procedures, has established an independent nonprofit corporation that in June will begin identifying "centers of excellence" deemed most qualified to do the complicated operations. The group is also gathering scientists at Georgetown University next month in the hopes of reaching a consensus on the risks and benefits of the treatment.

The rising concerns about stomach surgery illustrate the uncertainties that can occur with the emergence and proliferation of new surgical procedures, which often do not undergo the same level of testing, scrutiny and government oversight as new drugs or medical devices.

In addition, the debate over whether insurers should pay for the surgery illustrates the tension that is mounting as the obesity epidemic adds billions of dollars to the nation's medical bill. Millions of Americans already meet the criteria for the operation, which costs about $25,000, and millions more are expected to join those ranks as obesity rates soar.

"Insurance companies are feeling the first pressure of the increasing costs of the rising obesity epidemic from this procedure," said Roland Sturm, who studies the economic impact of obesity for the Rand Corp., a private research organization. "If we look into the future, the rising obesity epidemic will continue to have tremendous effects on health care costs. It's an astonishingly big factor. And it's only going to get bigger."

As the number of obese Americans has soared and new, less invasive laparoscopic versions of stomach surgery have been introduced, the number of people undergoing the operations has skyrocketed, spurred by the lack of effective alternatives and by celebrity patients such as NBC's "Today" show weatherman Al Roker. The number of surgeries shot up from about 16,000 a year in the early 1990s to an estimated 103,000 in 2003 -- and is expected to approach 150,000 this year, making it one of the fastest-growing procedures. Many centers report long waiting lists.

Surgeons perform several variations, but all involve sharply restricting the size of the stomach, either by stapling most of it closed or sealing it off with elastic bands and bypassing portions of the digestive system to reduce the number of calories that can be absorbed. The procedures can enable severely obese people to lose hundreds of pounds, alleviating disabilities and preventing, even sometimes reversing, serious health problems, most notably diabetes and high blood pressure.

But the operations are complicated, and patients are prone to life-threatening complications, including bleeding, blood clots, leakages and infections. Even if they have no serious complications, patients often experience unpleasant side effects, including a phenomenon known as "dumping" -- nausea, vomiting and diarrhea -- when they overeat. As a result, patients have to undergo intensive counseling and monitoring to make sure they eat appropriately and do not suffer nutritional deficiencies.

"It's extremely difficult surgery," said Paul Ernsberger, an associate professor of nutrition at Case Western Reserve University. "Even when it's done perfectly, there can be a lot of problems."

According to federal guidelines issued in 1991, the procedure is supposed to be performed only on people who are at least 100 pounds overweight – and primarily on those who are also suffering severe health problems because of their weight. While most people getting the procedure probably meet those criteria, there is concern that increasing numbers of people who weigh less are also undergoing the procedure.

"Many people who are not morbidly obese are trying to get this procedure. It's rapidly viewed as the answer to obesity, and more and more say, 'I can get surgery done as an answer to my problem,' " said Barry Schwartz of Blue Cross and Blue Shield of Florida. "We've actually seen a couple of patients who decided with their doctor that they would eat more so they could qualify. It's perverse."

Schwartz and other critics say the surge in popularity is enticing some hospitals and surgeons to try to capitalize on the interest.

"Many hospitals and physicians see this as a cash cow," Schwartz said. "We've seen surgeons who did a weekend course and then started doing this high-risk surgery. Make no mistake about this: This is high-risk surgery. The quality of service is going down, and the risk to patients is going up."

Some researchers also question the reliability of the data on the safety and effectiveness of the procedures.

"We don't have quality longer-term studies that give us good data on long-term safety and effectiveness," said Frank Lefevre, an associate professor of medicine at Northwestern University who evaluated the procedures for the Blue Cross and Blue Shield Association.

Already alarmed by skyrocketing health costs overall, a number of insurers, including Blue Cross and Blue Shield of Florida and Nebraska and Humana Inc., are discontinuing coverage for the operations.

"We've had an explosion in obesity and an explosion in the demand for quick fixes, if you will, to the problem of obesity," said Helen Darling, president of the National Business Group of Health, which represents major corporations on health issues. "It's beginning to dawn on insurance companies and employers that even after the surgery, there are a lot of big expenses and a lifetime of care. Many employers and insurance companies feel this is just not affordable today."

Some experts liken the situation to what happened with bone marrow transplants for breast cancer in the 1990s, when terminally ill breast cancer patients clamored for the procedure until carefully designed studies finally showed it did not save lives.

"Whenever a new technique seems to be providing benefit, it tends to proliferate," said Jonathan Moreno, a University of Virginia bioethicist who studies surgical procedures. "Oftentimes, these things gradually become the standard of care without going through any studies."

Proponents of the surgery say the procedures have undergone extensive study and have been clearly shown to help patients, enabling many to shed one-third to one-half of their excess body weight or more and keep it off for many years.

"I think these insurance companies may be using this as an excuse to avoid their responsibility. They think they can get away with this because of the prejudice that's out there for people who are obese," said Harvey Sugerman, president of the American Society for Bariatric Surgery. "I think it's a travesty."

For patients who have been suffering for years and been unable to lose weight despite repeated diets and exercise regimens, the operations are life-altering, he said. "It's an amazing operation. It's hard to describe how helpful it is to these patients. You have a patient who comes in who can hardly breathe, their legs are all swollen up, they have diabetes and high blood pressure, and they come back to you in three months, and they're all gone. They feel wonderful."

While the procedures can be dangerous, Sugerman and others said that for appropriate patients, the benefits clearly offset the risks, which are on a par with the dangers of operations for other life-threatening conditions involving seriously ill patients.

"It's actually surprising how good the results are," said David R. Flum, a University of Washington surgeon. "If you look at all the options available for the treatment of obesity, we know one thing for sure: Nonsurgical approaches, even the most radical approaches, even the most aggressive nonsurgical approaches, are horribly ineffective."

But Flum and some other experts acknowledge the complication rates are unclear. Most published studies have involved highly experienced surgeons operating on ideal candidates. Some research indicates the complication and mortality risks may be much higher than reported, especially as less experienced surgeons begin performing the procedures on a wider spectrum of patients.

"We really don't know what's happening in the real world, and there's a lot of reason to be really worried about that," said Flum, who is helping evaluate the procedures for the NIH consortium. "In the real world, surgeons may do many fewer patients per year. They are learning the procedure. Or picking patients who may not do as well. A lot of things have got us worried."

http://www.washingtonpost.com

[NA1]"MCVI" is the more commonly known name for the group of physicians in Miami of which Dr. Powell, the filter implanting physician, is a part.
[NA2]No. The number is not 6 now. This is the data that is in the product's package insert (IFU). These facts still hold for the Canadian cohort.
[NA3]I'm not sure which papers are being referenced here (the first and second papers, specifically)
[NA4]I think this entire 1st sub-bullet is problematic. We don't know how many filter have been implanted; we only know how many we've sold. Also, "success" really depends on how you look at it. Does lack of complaints equal success?
[NA5]An IVC filter does not prevent blood clots; it just keeps it from traveling to the lungs.
[NA6]Do we want to add that this was at post-mortem?
[NA7]Probably need to addd additional comments about the initial conclusions of this incident.
[NA8]Probably need to add additional comments about the initial conclusions of this incident.
[NA9]Include that this was at post-mortem?
[NA10]Include that this was at post-mortem?
[NA11]Probably need to add additional comments about the initial conclusions of this incident.
[NA12]Although blood clots can originate in the arms, Recovery is not indicated for SVC use, therefore it does nothing to prevent PE from upper-extremity DVT (when used as labeled)
[NA13]Must stay away from calling all physicians "surgeons". The specialty with the largest proportion of IVC filter use is Interventional Radiologists. Filters are also used by cardiologists.
[NA14]Although blood clots can originate in the arms, Recovery is not indicated for SVC use, therefore it does nothing to prevent PE from upper-extremity DVT (when used as labeled)
[NA15]Must stay away from calling all physicians "surgeons". The specialty with the largest proportion of IVC filter use is Interventional Radiologists. Filters are also used by cardiologists.
[NA16]Although blood clots can originate in the arms, Recovery is not indicated for SVC use, therefore it does nothing to prevent PE from upper-extremity DVT (when used as labeled)

Internal Q&A: CR Bard Recovery Vena Cava Filter
Version May 10, 2004

Note: Internal Q&A to be used by approved Corporate spokespeople to respond consistently to inquiries from media. Not to be handed out externally to any audiences.

1. *What is the Recovery Vena Cava Filter and how does it work?*

   Introduced in April 2003, the Recovery® Nitinol Vena Cava Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted percutaneously in the inferior vena cava (IVC). The Recovery Filter has the additional feature of being able to be percutaneously removed after implantation. The Recovery Filter may be used as a permanent or temporary device.

   The Recovery Filter System consists of the Filter and Delivery System. The Filter consists of twelve nitinol wires emanating from a central sleeve. These twelve wires form two levels of filtration. The device is intended to be used in vena cava with diameters of up to 28 mm and is currently available for femoral vein approach only.

2. *What is the difference between a retrievable vena cava filter and a non-retrievable vena cava filter?*

   A non-retrievable vena cava filter is indicated for permanent use; once inserted into the vena cava, the device is left in place. On the other hand, after implantation, a retrievable vena cava filter may be removed at the physician's discretion, usually once the risk of a venous thromboembolism or pulmonary embolism is reduced.

   The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed. The Recovery Filter's hooks allow the filter to remain rigid and provide anchoring, but deform when the filter apex is engaged with the specially designed removal device (Recovery Cone® Removal System) and pulled upward.

3. *What is the marketshare of the Recovery Filter for the overall vena cava filter market?*

   6% (in units) .

4. *What is the marketshare of the Recovery Filter for the retrievable vena cava filter market?*

   We have sold over 8,500 units of the Recovery Filter to date. We understand that the overall total market for all retrievable and non-retrievable vena cava filters is approximately130,000 units.

   While the retrievable segment of the vena cava filter market is rapidly growing, for the past 12-month period, the market is estimated to have been approximately 30,000 units. Of that, Recovery had a 25% share.

5. *How many Recovery Vena Cava Filters have been inserted in the US and, separately, around the world?*

   [NAI] We have sold over 8,500 units of the Recovery Filter to date

6. *Do you have any studies that prove the safety and efficacy of the Recovery Vena Cava Filter?*

   Yes. We have studies that prove the safety and efficacy of the Recovery Vena Cava Filter. For example, the Recovery Filter was safely and effectively used by an investigator and two colleagues at six Toronto area hospitals. In this Toronto study, of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with filters in place of causes unrelated to filter placement or retrieval.

   In addition, the Recovery Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

   We are happy to provide a full listing of study summaries to you.

7. *What are pulmonary emboli and what are the risks associated with them?*

Pulmonary emboli are blood clots that form in large veins, such as those in the thigh, and then travel to the lungs. In the lungs, they block blood flow, which can cause shortness of breath, chest pain, faintness, low blood pressure, lung damage, and in severe cases, sudden death. Such clots are particularly likely to form in a variety of unusual circumstances, including prolonged immobility, after hip surgery, after major traumatic surgery and in obese individuals after weight reduction ("bariatric") surgery.

8. *Under what circumstances would the Recovery Vena Cava Filter be used?*

The Recovery Filter is indicated for use in the prevention of recurrent pulmonary embolism through permanent or temporary placement in the vena cava in the following situations:

a. Pulmonary thromboembolism when anticoagulants are contraindicated.
b. Failure of anticoagulant therapy for thromboembolic disease.
c. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The device is intended to be used in vena cava with diameters of up to 28 mm, and when clinically indicated, the Recovery Filter may be percutaneously removed at the physician's discretion.

9. *How is the Recovery Vena Cava Filter inserted?*

The Recovery Vena Cava Filter is inserted into a femoral venous access route during a procedure performed by a medical professional. The "Instructions for Use" provide more information about the insertion and removal procedures.

10. *Who designed the Recovery Filter?*

Bard purchased the product design and manufacturing from a valued partner. Bard has thoroughly assessed and tested the product and stands behind its design in every way.

11. *What is the name of the company that designed the Recovery Filter?*

That information can be found in public records.

12. *Have there been any design changes in the Recover Filter over the years?*

There have been changes in the delivery system but not the filter itself.

13. *What level of expertise is required to properly insert the Recovery Vena Cava filter?*

Physicians who have undergone training for minimally invasive, endovascular procedures can place the Recovery Vena Cava Filter. These physician specialties include, but are not limited to, interventional radiologists, vascular surgeons, trauma surgeons, cardiologists, and general surgeons as well as residents and fellows of those disciplines.

Placement of the Recovery Filter, in general, is quick (10 minutes) if there is easy access to the femoral vein. The procedure has been described by physicians as easy to perform.

14. *How are doctors trained on the proper use of the Recovery Vena Cava filter? How extensive is this training?*

There is currently no formal training requirement imposed on users by Bard for filter insertion.

Filter retrieval is under a limited market release process which requires the user to either 1) attend a one-day hands-on workshop or 2) have a qualified sales representative present for the initial three (3) cases.

15. *What are the potential complications associated with the Recovery Vena Cava filter?*

Potential complications observed for all types of inferior vena cava filters including the Recovery Filter include filter migration, perforation of the vena cava wall by filter legs, and vena caval occlusion or obstruction.

16. How often does the Recovery Filter actually migrate?

As of the end of April 2004, out of 8,500 devices sold in the U.S., there have been six reported cases of migration.

There is risk of migration with any vena cava filter. There is no single definitive cause of filter migration. The buildup of a large clot or series of clots, the movement of the walls of the vena cava due to respiration and improper filter placement can cause migration. There are also other factors that could potentially cause a filter to migrate, and many questions still remain as to exactly why filters migrate. In addition, filters may appear to have migrated due to x-ray equipment variation, patient position, measurement error, and respiration.

17. How does your rate of migration for the Recovery Filter compare to that of your retrievable and noretrievable device competitors?

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

18. Are retrievable filters more susceptible to migration than non-retrievable filters?

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

19. What causes filter migration?

Filter migration occurs whenever the force trying to move the filter exceeds the holding power of its fixation arms. A properly placed vena cava filter can constrain a significant amount of blood clot, but large blood clots can overwhelm the filter's retentive capabilities. Other recognized causes of filter migration include improper implantation technique, unusual patient exertion (such as straining at bowel movements) and fracture or failure of the filter wires. All marketed filters in the US have reported instances of filter migration. .[NA3]

It also is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

20. *What is the "acceptable" rate of migration for vena cava filters?*

Realistically, migrations do occur. All marketed filters in the US have reported instances of filter migration. Experts continue to debate what constitutes an acceptable rate of migration, relative to the risk of not using the filter.

21. *What are the dangers associated with filter migration?*

Most filter migrations are harmless to the patient and include filter movement of a few centimeters. In unusual cases, a filter containing a large amount of clot may migrate through the bloodstream to the lungs or heart. These complications can require surgical removal of the filter and clot, and rarely cause death. Without the filter, this amount of clot would generally have passed directly to the lungs or heart, causing substantial harm on its own.

22. *If a retrievable filter provides the added benefit of retrievability and creates no greater risk of migration or other complications, why would any physician choose to use a non-retrievable filter?*

I cannot speak on behalf of physicians but understand that non-retrievable filters can be less expensive than retrievable filters. Presumably, if a physician believes there will be no reason to remove the filter, it might make sense to choose the less expensive non-retrievable option. However, there is no way to predict with 100% accuracy whether or not a patient is going to require the filter for the rest of his/her life. I understand though, that an increasing number of physicians choose retrievable over non-retrievable vena cava devices after gaining greater understanding of the safety, efficacy and added benefits of retrievable filters.

23. *Migration of a Recovery Filter was recently listed as the cause of death for a patient in Miami. Can you tell us why this specific filter migrated?*

As with any report of an adverse event, we took an immediate, systematic approach to determine the cause and events. With this particular event, we formed a multi-disciplinary team to thoroughly investigate the incident. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event.

We do know that there was a very large blood clot or an accumulation of blood clots, measuring 10 cm in length and 3 cm in diameter, which deposited around the filter over a period of several days. The large blood

clot or accumulated clots may have enveloped the filter and traveled through the bloodstream to the patient's heart, causing sudden death. The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.

24. *If filter migration was not the cause of death, why was it listed as the cause of death on the coroner's report?*

I cannot speak for the coroner. What I can tell you at this point, however, is that from the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event.

We do know that there was a very large blood clot or an accumulation of blood clots, measuring 10 cm in length and 3 cm in diameter, which deposited around the filter over a period of several days. The large blood clot or accumulated clots may have enveloped the filter and traveled through the bloodstream to the patient's heart, causing sudden death. The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.

25. *Is it possible that the filter was not inserted properly?*

I do not want to speculate on the role of filter placement in this incident. What I can say is that, while improper filter insertion or placement can cause migration, we believe a blood clot as large as the one that enveloped the filter in this incident can very likely cause death.

26. *Is there any reason to believe that the Recovery Filter is to blame for this patient's death?*

I do not want to speculate on the role of the Recovery Filter in this incident. What I can say is that we believe a blood clot as large as the one that enveloped the filter in this incident can very likely cause death.

27. *Has Bard been sued by the family of the deceased?*

Not to my knowledge.

28. *Has the Recovery Filter been associated with other deaths in the past?*

Yes. A patient in Lacrosse, Wisconsin died with a Recovery Filter in place. The cause of death cited was pulmonary embolism.

29. *Has Bard been sued because of death or damage caused by migration in the past?*

Not to my knowledge.

30. *In the late 80's, weren't Bard's balloon angioplasty medical devices permanently pulled from the market because of safety issues?*

The Recovery Vena Cava Filter products we are discussing today are considered safe and effective by the medical community and had nothing to do with the situation you mentioned. In the late 1980s, a C.R. Bard subsidiary named USCI manufactured balloon angioplasty catheters, which were taken off the market. The details of criminal and civil lawsuits associated with these catheters are well documented. USCI was sold and no individual involved in those incidents is currently with the company. Since then, the entire executive management team has been changed. Today, Bard maintains an excellent working relationship with the FDA.

31. *What other Bard products have been pulled from the market and for what reasons?*

Bard has been in business for nearly a century, and we are known for our commitment to provide innovative, life-enhancing medical technologies to our patients. Holds can occur for a variety of safety and non-safety related reasons. In cases in which safety was a concern, products were placed back on the market after further testing. The Recovery Vena Cava Filter products we are discussing today are considered extremely safe and effective by the medical community.

32. *What Bard products have been put on hold in the past two years?*

As a course of company policy, we do not discuss previous product recalls. When such a recall occurs, we quickly and proactively provide necessary information to impacted customers, physicians and patients. The Recovery Vena Cava Filter products we are discussing today are considered safe and effective by the medical community.

33. *Have you pulled any products over the past five years that have not been put back on the market? If yes, why were they pulled?*

As a course of company policy, we do not discuss previous product recalls. When such a recall occurs, we quickly and proactively provide necessary information to impacted customers, physicians and patients. The Recovery Vena Cava Filter products we are discussing today are considered safe and effective by the medical community.

34. *How does Bard receive and respond to reports of adverse events associated with its Recovery vena cava filter?*

With any report of an adverse event, we take an immediate, systematic approach to thoroughly investigate the incident. Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility of developing and delivering safe medical devices.

35. *Are there any physicians I can talk with about the safety and efficacy of the Recovery Vena Cava Filter?*

John A. Kaufman, MD [?]
Anthony C. Venbrux, MD [?]
Gary S. Cohen, MD
Thomas B. Kinney, MD
Christoph A. Binkert, MD
William S. Rilling, MD

36. *Appropriate question must be developed and addressed regarding MAUDE database. Space holder question: Can you explain the data in the FDA's MAUDE database for the Recovery Filter as compared to other vena cava filters?*

[PLEASE PROVIDE.]

[NA1]It is impossible to determine the number of filters that have actually been placed. The only data point that we can provide is the number that have been sold.
[NA2]Again, this is difficult to determine. All we know is how many have been sold. Also, does lack of complaints mean that it was safely used?
[NA3]It is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.
[NA4]This is not necessarily true.

External Q&A: CR Bard Recovery Vena Cava Filter
Version May 10, 2004

[Note: External Q&A are intended to be used by Bard Core and Audience Response Team members to consistently respond to questions from external audiences, and can be handed out to media, customers, physicians, suppliers, investors and other Bard audiences.]

1. *What is the Recovery Vena Cava Filter and how does it work?*

   Introduced in April 2003, the Recovery® Nitinol Vena Cava Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted percutaneously in the inferior vena cava (IVC). The Recovery Filter has the additional feature of being able to be percutaneously removed after implantation. The Recovery Filter may be used as a permanent or temporary device.

   The Recovery Filter System consists of the Filter and Delivery System. The Filter consists of twelve nitinol wires emanating from a central sleeve. These twelve wires form two levels of filtration. The device is intended to be used in vena cavae with diameters of up to 28 mm and is currently available for femoral vein approach only.

2. *What is the difference between a retrievable vena cava filter and a non-retrievable vena cava filter?*

   A non-retrievable vena cava filter is indicated for permanent use; once inserted into the vena cava, the device is left in place. On the other hand, after implantation, a retrievable vena cava filter may be removed at the physician's discretion, usually once the risk of a venous thromboembolism or pulmonary embolism is reduced.

   The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed. The Recovery Filter's hooks allow the filter to remain rigid and provide anchoring, but deform when the filter apex is engaged with the specially designed removal device (Recovery Cone® Removal System) and pulled upward.

3. *How many Recovery Vena Cava Filters have been inserted in the US and, separately, around the world?*

   We have sold over 8,500 units of the Recovery Filter to date

4. *Under what circumstances would the Recovery Vena Cava Filter be used?*

   The Recovery Filter is indicated for use in the prevention of recurrent pulmonary embolism through permanent or temporary placement in the vena cava in the following situations:
   a. Pulmonary thromboembolism when anticoagulants are contraindicated.
   b. Failure of anticoagulant therapy for thromboembolic disease.
   c. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
   d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

   The device is intended to be used in vena cava with diameters of up to 28 mm, and when clinically indicated, the Recovery Filter may be percutaneously removed at the physician's discretion.

5. *Do you have any studies that prove the safety and efficacy of the Recovery Vena Cava Filter?*

   Yes. We have studies that prove the safety and efficacy of the Recovery Vena Cava Filter. For example, the Recovery Filter was safely and effectively used by an investigator and two colleagues at six Toronto area hospitals. In this Toronto study, of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with filters in place of causes unrelated to filter placement or retrieval.

   In addition, the Recovery Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

   We are happy to provide a full listing of study summaries to you.

6. *What are pulmonary emboli?*

Pulmonary emboli are blood clots that form in large veins, such as those in the thigh, and then travel to the lungs. In the lungs, they block blood flow, which can cause shortness of breath, chest pain, faintness, low blood pressure, lung damage, and in severe cases, sudden death. Such clots are particularly likely to form in a variety of unusual circumstances, including prolonged immobility, after hip surgery, after major traumatic surgery and in obese individuals after weight reduction ("bariatric") surgery.

7. *How is the Recovery Vena Cava Filter inserted?*

The Recovery Vena Cava Filter is inserted into a femoral venous access route during a procedure performed by a medical professional. The "Instructions for Use" provide more information about the insertion and removal procedures.

8. *Have there been any design changes in the Recover Filter over the years?*

There have been changes in the delivery system but not the filter itself.

9. *How are medical professionals trained on the proper use of the Recovery Vena Cava filter?*

There is currently no formal training requirement imposed on users by Bard for filter insertion.

Filter retrieval is under a limited market release process which requires the user to either 1) attend a one-day hands-on workshop or 2) have a qualified sales representative present for the initial three (3) cases.

10. *Are there potential complications associated with vena cava filters?*

Potential complications observed for all types of inferior vena cava filters including the Recovery Filter include filter migration, perforation of the vena cava wall by filter legs, and vena caval occlusion or obstruction.

11. What is the "acceptable" rate of migration for vena cava filters?

Realistically, migrations do occur. All marketed filters in the US have reported instances of filter migration. Experts continue to debate what constitutes an acceptable rate of migration, relative to the risk of not using the filter.

12. What causes filter migration?

Filter migration occurs whenever the force trying to move the filter exceeds the holding power of its fixation arms. A properly placed vena cava filter can constrain a significant amount of blood clot, but large blood clots can overwhelm the filter's retentive capabilities. Other recognized causes of filter migration include improper implantation technique, unusual patient exertion (such as straining at bowel movements) and fracture or failure of the filter wires. All marketed filters in the US have reported instances of filter migration. .[NA2]

It also is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

13. How does your rate of migration for the Recovery Filter compare to that of your retrievable and noretrievable device competitors?

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

14. Is CR Bard currently involved in any lawsuits surrounding the Recovery Vena Cava filter?

No

15. Has Bard been sued because of death or damage caused by migration of a Recovery Vena Cava Filter in the past?

No

16. *How does Bard receive and respond to reports of adverse events associated with its Recovery vena cava filter?*

With any report of an adverse event, we take an immediate, systematic approach to thoroughly investigate the incident. Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility of developing and delivering safe medical devices.

17. *Are there any physicians I can talk with about the safety and efficacy of the Recovery Vena Cava Filter?*

John A. Kaufman, MD
Anthony C. Venbrux, MD
Gary S. Cohen, MD
Thomas B. Kinney, MD
Christoph A. Binkert, MD
William S. Rilling, MD

[NA1]Impossible to know how many have been placed. We have sold over 8500 as of the end of April.
[NA2]It is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.
[NA3]It is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

EXHIBIT 39

John Lehmann

From: John Lehmann [jlehmann@lehmannthomas.com]
Sent: Thursday, April 15, 2004 3:07 PM
To: 'Lee Lynch'; 'Glass, Holly'; 'Passero, Donna'; 'Hudnall, Janet'; 'Jones, Kellee'
Cc: 'Kimberly Ocampo'
Subject: RE: Crisis Plan and Supporting Documents for your review

Lee I have reviewed the various documents attached to your email.

My telephones are as follows:
O: 617 489 7080
H: 508 358 5365
C: 508 341 8942

Our overall simple message needs to be:

1. A properly placed filter can resist the force of a fair amount of blood clot, but that large clots and the forces of exertions such as bowel movements can overwhelm any filter's retentive capability, resulting in migration.

2. This is true for all IVC filters.

3. This leads into the two key facts in this case:
   a. that the RF is a well designed and tested IVC filter that was properly placed and intact, and
   b. that the blood clot was massive and additionally propelled by straining at stool.

==> Bottom line: good filter, severe case, bad outcome, deep regret.

This is the simple story we should repeat again and again.

Comparison with other filters is problematic in many ways, and we should avoid / downplay this as much as possible. When pressed, we simply paraphrase what was said in the Health Hazard, that " Estimates based on available data suggest that there is no significant difference in the rates of these complications between any of the devices currently marketed in the U.S., including the Recovery device."

As to review of the specific documents you forwarded:

The statement on page 20 0f the main communications plan as follows:
"

- Extensive migration resistance testing conducted ~~competitors~~ showed that the Recovery Filter was just as ~~resistant~~ or more resistant to migration than all retrievable and non-retrievable competitors (MUST CONFIRM)."

is not
entirely accurate and does need revision. Should be discussed with BPV R&D and QA folks who've done the com at largest recommended IVC diameters the migration resistance drops substantially. BTW, I would think that the content herein does need review by John DeFord, Chris Ganser et al; I am presuming that you are doing this separately or at a later stage of drafting.

On page 21, the author has noted:

1. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event.

[OR CAN WE SAY: While the Recovery Filter did migrate, we believe the underlying cause of death was the accumulation and migration of a very large pulmonary embolism. An enormous blood clot, measuring 10 cm in length and 3 cm in diameter, was deposited around the filter over a period of several days. The clot was of such a massive size that it enveloped the filter and traveled through the bloodstream to the man's lungs, causing death.]

From the point of view of patient privacy, it is confidential information regarding the pathological findings, cause of death etc., so I am not sure we are entitled to disclose such information, with the exception of prior legitimate disclosure by others (such as family members). I would guess (needs legal concurrence) that we can disclose the testing results that we have had performed in relation to the filter, such as the RF was entirely intact and functional. Whether we can mention blood clot or size of clot is a legal question relating to HIPAA issues etc.

For the Internal Q&A document, I would recommend changing #7 to the following text:

> Pulmonary emboli are blood clots that form in large veins, such as those in the thigh, and then travel to the lungs. In the lungs, they block blood flow, which can cause shortness of breath, chest pain, faintness, low blood pressure, lung damage and in severe cases, sudden death. Such clots are particularly likely to form in a variety of unusual circumstances, including prolonged immobility, after hip surgery, after major traumatic injury and in obese individuals after weight reduction ("bariatric") surgery.

For the Internal Q&A document, the answer to Question #10 'who designed the RF' as 'NMT' is really not helpful to Bard, and certainly not to NMT. Bard bought, approved and sells the RF, and owns the design and its merits and demerits. Dinging NMT won't help the PR case, and will certainly piss off NMT. I'd find another way to handle this issue, such as "Bard purchased the product design and manufacturing from a valued partner, and has thoroughly assessed and tested the product, and stands behind its design in every way." or some such similar supportive and positive statement.

For the Internal Q&A document, Question #13 on physician training, be very careful on this one. It's not what you think you're doing, or what you told the FDA, but what you are actually currently doing. Get the straight story from the Sales force and don't dress it up.

For internal Q&A, Question #14 on complications, recommend changing to:

> Potential complications observed for all types of inferior vena cava filters including the Recovery Filter include filter migration, perforation of the vena cava wall by filter legs, and vena caval occlusion or obstruction.

For Internal Q&A #15, the answer (text about various possible causes of migration) is not at all responsive to the question (about rate of migration for RF). The answer to #16 is the answer. Why don't you get rid of the A to #15 and the Q for #16, and combine the remains.

For Internal Q&A #17 - 18 on migration resistance testing, I wouldn't raise this subject if at all possible. It would be a most unusual reporter that will get this far. The testing data I saw in Arizona showed that altho RF was certainly within the boundaries of devices tested, in larger veins it was near the bottom. I would avoid as much as possible getting into this subject, because I'm not sure others would agree with the conclusion that "Recovery Vena Cava Filter was just as or more resistant to migration than all retrievable and non-retrievable competitors"

Internal QA& #19 ditto

Internal Q&A #20. I would change the text for #20 to:

> Filter migration occurs whenever the force trying to move the filter exceeds the holding power of its fixation arms. A properly placed vena cava filter can constrain a significant amount of blood clot, but large blood clots can overwhelm the filter's retentive capabilities. Other recognized causes of filter migration include improper implantation technique, unusual patient exertion (such as straining at bowel movements) and

fracture or failure of the filter wires. All marketed filters in the U.S. have reported instances of filter migration.

[If asked about Recovery Vena Cava Filter cases in which migration occurred, also add the following to the response: Of the six reported cases of the Recovery Filter migrating, five were caused by blood clots and one was caused by improper filter insertion.]

Internal Q&A #22 as follows:

1. *What are the dangers associated with filter migration?*

Most filter migrations are harmless to the patient and include filter movement of a few centimeters. In unusual cases, a filter containing a large amount of clot may migrate through the bloodstream to the lungs or heart. These complications can require surgical removal of the filter and clot, and rarely cause death. Without the filter, this amount of clot would have generally have passed directly to the lungs, causing substantial harm on its own.

INternal Q&A #24 - 27: I'd like to get a read on the HIPAA implications of discussing any clinical information regarding this patient. If we are able to discuss such things, then the text for these needs some significant revision. If not (which might be preferable) we have to say that we cannot discuss confidential patient information in response to all such questions as to causation, death certificates text, etc. Let's discuss once Donna has ruled on what disclosure is permissible in various circumstances.

External Q&A's:
#6 on what is a pulmonary embolus: see remarks above for Internal Q&A #7

#9 on training: see Internal Q&A #13 above

#10 on complications: see Internal QA& #14 above

#12 on causes of filter migration: see Internal Q&A #20 above

#13 on comparative migration resistance: see multiple caveats above

An area that is not covered is the MAUDE database. If we get a reporter pressing questions on the number of reports, then we will have to deal with this sticky area. That means we have to have sales estimates, and tabulations of MAUDE entries (as already prepared by BPV staff) and calculations of rates; as well as someone comfortable with quantitative presentation skills and credibility.

RE medical literature summaries: can't comment, I'm on the road w/o the references. Practically speaking, we need to make sure that our physician spokespersons have all these references and the summary in a well organized binder, so that they can refer to them rapidly.

Hope this helps.

Regards, John Lehmann

From: Lee Lynch [mailto:LLynch@HillandKnowlton.com]
Sent: Tuesday, April 13, 2004 6:07 PM
To: 'Glass, Holly'; 'Passero, Donna'; 'John Lehmann'; Hudnall, Janet; 'Jones, Kellee'
Cc: Kimberly Ocampo
Subject: Crisis Plan and Supporting Documents for your review

PRIVILEGED AND CONFIDENTIAL

Hi everyone -

Through conversations with Janet, Donna and Holly, we have secured enough information to create complete initial drafts of the Recovery Vena Cava Filter Crisis Plan and corresponding documents; each of these documents is attached for your review:

- Full Crisis Plan. Included in the Appendix section of the Crisis Plan are additional documents for your review, including:
  - General Key Messages
  - Miami incident-specific key messages
  - General Letter to the Editor
  - Miami incident-specific Letter to the Editor
- Internal Q&A
- External Q&A
- Medical Study Summaries

We'd like to ask you to review all of the documents this week, then join us for a call to go through your revisions sometime early next week. Can you let us know your availability on Monday and Tuesday of next week?

Questions for consideration and feedback are highlighted in yellow within the documents.

In addition, we have a number of questions we are hoping to have the following individuals answer directly to us by e-mail this week, including:

For Kellee Jones:

- Contact information for Chris Ganser and Doug Uelmen

For Janet Hudnall:

- Mobile number
- Is it OK to add Carol Stone under the key contact for the Field Sales Reps in the Audience Response Team section of the Crisis Plan?
- Are there any physicians NOT paid by Bard who can serve as spokespeople? If not, could you follow up with Drs. Venbrux and Kaufman regarding their interest and availability? To that end, please confirm that these physicians indeed have been paid by Bard for training and speaking.
- Is it OK to add the Society of Vascular Surgeons as an ally organization?
- Can you provide us with the following studies: Kaufman and Venbrux for FDA approval and the Special Access Canadian study?
- Are there any other human studies to add to the "Medical Study Summaries"?

Many thanks for your help! Lee Lynch and Kimberly Ocampo, H&K

EXHIBIT 40

From: Greer, Jason [/O=BARD/OU=MHL AG/CN=RECIPIENTS/CN=JGREER]
Date: 3/16/2006 2:32:37 AM
To: Hudnall, Janet [Janet.Hudnall@crbard.com]
Subject: say crazy
Attachments: image001.jpg, image002.jpg

Hey, when you go about choosing speakers for filter breakouts, please consider Nicole. She is doing some really cool stuff…some of it I can talk about…some I can't. However, her knowledge of low molecular weight heparin and heparin is allowing her to take over the market. Another guy that knows his Shiite on filters and is worth considering is Fecher. I swear, the guy is a walking encyclopedia of filters. He is a young John Timko. He wakes, eats, sleeps filters.

I'm going to call you tomorrow……..crazy.

We were on vacation in San Antonio. It was so awesome. The kids went to Sea World and Six Flags. The Westin there has an awesome set of pool just for the kids. It was 90 degrees but pleasant. I even took a nap. I've take about 10 of those in my adult life.

BTW, you know what I was thinking about today? I was thinking how far we've come in a year as far as filter problems. I know we are having a few problems but do you freaking remember what it was like a year ago? Do you remember what it was like 2 years ago? I don't know if it can ever get any worse. You weathered the storm as well as anyone, anyone could have. If you do decide to interview for new positions, you better document what you did because I don't think there are many better business case studies for a terrible situation that was held together with scotch tape, smoke, mirrors, crying, etc. You should be pretty proud of yourself.

Also, Ben is going to work with Dave Stearn at Cardiomim(sp?). Don't tell him about the affair. It's over.

Jason Greer

District Sales Manager

901.485.1485 Fax 800.657.1498

www.bardpv.com